Reunión Extraordinaria de la Comisión Nacional de Inmunización (CoNaIn)

Vacuna Sinopharm

Dr. Pablo Bonvehí

1 de marzo de 2021

Agenda

- Vacunas Sinopharm estudios Fase 1 y 2
- Ensayos clínicos en desarrollo
- Datos de Fase 3
- Aprobación
- Manual del Vacunador

Vacuna virus inactivado Sinopharm

Cepa WIV04

Aislada de paciente del hospital Jinyitan, Wuhan, China

JAMA | Preliminary Communication

Effect of an Inactivated Vaccine Against SARS-CoV-2 on Safety and Immunogenicity Outcomes

Interim Analysis of 2 Randomized Clinical Trials

Shengli Xia, BS; Kai Duan, PhD; Yuntao Zhang, PhD; Dongyang Zhao, BS; Huajun Zhang, PhD; Zhiqiang Xie, MD; Xinguo Li, MD; Cheng Peng, MD; Yanbo Zhang, MD; Wei Zhang, MD; Yunkai Yang, MD; Wei Chen, MSc; Xiaoxiao Gao, PhD; Wangyang You, MD; Xuewei Wang, MD; Zejun Wang, PhD; Zhengli Shi, PhD; Yanxia Wang, BS; Xuqin Yang, MD; Lianghao Zhang, MSc; Lili Huang, BS; Qian Wang, MD; Jia Lu, PhD; Yongli Yang, PhD; Jing Guo, PhD; Wei Zhou, PhD; Xin Wan, MD; Cong Wu, MD; Wenhui Wang, MD; Shihe Huang, PhD; Jianhui Du, MD; Ziyan Meng, MD; An Pan, PhD; Zhiming Yuan, PhD; Shuo Shen, PhD; Wanshen Guo, BS; Xiaoming Yang, MD

IMPORTANCE A vaccine against coronavirus disease 2019 (COVID-19) is urgently needed.

OBJECTIVE To evaluate the safety and immunogenicity of an investigational inactivated whole-virus COVID-19 vaccine in China.

INTERVENTIONS In the phase 1 trial, 96 participants were assigned to 1 of the 3 dose groups (2.5, 5, and 10 μg/dose) and an aluminum hydroxide (alum) adjuvant–only group (n = 24 in each group), and received 3 intramuscular injections at days 0, 28, and 56. In the phase 2 trial, 224 adults were randomized to 5 μg/dose in 2 schedule groups (injections on days 0 and 14 [n = 84] vs alum only [n = 28], and days 0 and 21 [n = 84] vs alum only [n = 28]).

DESIGN, SETTING, AND PARTICIPANTS Interim analysis of ongoing randomized, double-blind, placebo-controlled, phase 1 and 2 clinical trials to assess an inactivated COVID-19 vaccine. The trials were conducted in Henan Province, China, among 96 (phase 1) and 224 (phase 2) healthy adults aged between 18 and 59 years. Study enrollment began on April 12, 2020. The interim analysis was conducted on June 16, 2020, and updated on July 27, 2020.

MAIN OUTCOMES AND MEASURES The primary safety outcome was the combined adverse reactions 7 days after each injection, and the primary immunogenicity outcome was neutralizing antibody response 14 days after the whole-course vaccination, which was measured by a 50% plaque reduction neutralization test against live severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

RESULTS Among 320 patients who were randomized (mean age, 42.8 years; 200 women [62.5%]), all completed the trial up to 28 days after the whole-course vaccination. The 7-day adverse reactions occurred in 3 (12.5%), 5 (20.8%), 4 (16.7%), and 6 (25.0%) patients in the alum only, low-dose, medium-dose, and high-dose groups, respectively, in the phase 1 trial; and in 5 (6.0%) and 4 (14.3%) patients who received injections on days 0 and 14 for vaccine and alum only, and 16 (19.0%) and 5 (17.9%) patients who received injections on days 0 and 21 for vaccine and alum only, respectively, in the phase 2 trial. The most common adverse reaction was injection site pain, followed by fever, which were mild and self-limiting; no serious adverse reactions were noted. The geometric mean titers of neutralizing antibodies in the low-, medium-, and high-dose groups at day 14 after 3 injections were 316 (95% CI, 218-457), 206 (95% CI, 123-343), and 297 (95% CI, 208-424), respectively, in the phase 1 trial, and were 121 (95% CI, 95-154) and 247 (95% CI, 176-345) at day 14 after 2 injections in participants receiving vaccine on days 0 and 14 and on days 0 and 21, respectively, in the phase 2 trial. There were no detectable antibody responses in all alum-only groups.

CONCLUSIONS AND RELEVANCE In this interim report of the phase 1 and phase 2 trials of an inactivated COVID-19 vaccine, patients had a low rate of adverse reactions and demonstrated immunogenicity; the study is ongoing. Efficacy and longer-term adverse event assessment will require phase 3 trials.

TRIAL REGISTRATION Chinese Clinical Trial Registry Identifier: ChiCTR2000031809

JAMA. doi:10.1001/jama.2020.15543. Published online August 13, 2020

Vacuna Virus Inactivado Sinopharm cepa WIV04 - Reactogenicidad

Table 2. Adverse Reactions After 3 Doses in the Phase 1 Trial and 2 Doses in the Phase 2 Trial in the Safety Set[a]

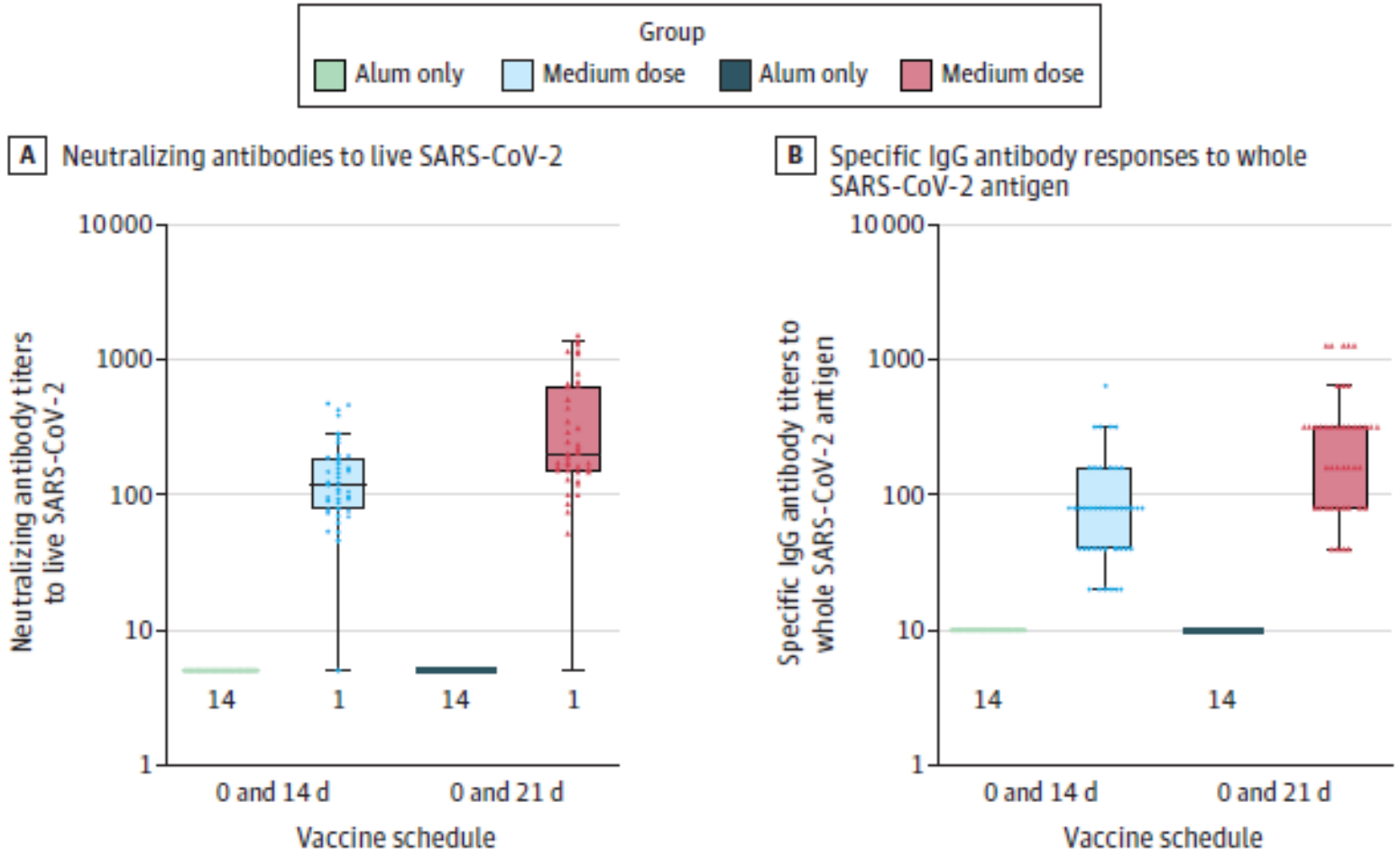
	Phase 1 clinical trial; 0, 28, and 56-d group				Phase 2 clinical trial			
					0 and 14-d Group		0 and 21-d Group	
Adverse reaction	Low dose (n = 24)	Medium dose (n = 24)	High dose (n = 24)	Alum only (n = 24)	Medium dose (n = 84)	Alum only (n = 28)	Medium dose (n = 84)	Alum only (n = 28)
0-7 d								
Total adverse reactions	5 (20.8)	4 (16.7)	6 (25.0)	3 (12.5)	5 (6.0)	4 (14.3)	16 (19.0)	5 (17.9)
Systemic reactions	0	3 (12.5)	1 (4.2)	1 (4.2)	4 (4.8)	2 (7.1)	4 (4.8)	2 (7.1)
Coughing	0	0	0	0	1 (1.2)	0	0	0
Diarrhea	0	0	0	0	0	0	1 (1.2)	0
Fatigue	0	1 (4.2)	0	0	1 (1.2)	0	0	0
Fever	0	1 (4.2)	1 (4.2)	0	4 (4.8)	1 (3.6)	2 (2.4)	1 (3.6)
Headache	0	0	0	0	1 (1.2)	1 (3.6)	0	1 (3.6)
Nausea and vomiting	0	1 (4.2)	0	1 (4.2)	0	0	1 (1.2)	1 (3.6)
Pruritus (noninoculated site)	0	0	0	0	0	0	0	1 (3.6)
Local reactions	5 (20.8)	1 (4.2)	6 (25.0)	2 (8.3)	2 (2.4)	3 (10.7)	13 (15.5)	4 (14.3)
Itching	0	0	0	0	0	0	1 (1.2)	1 (3.6)
Pain	5 (20.8)	1 (4.2)	6 (25.0)	2 (8.3)	2 (2.4)	3 (10.7)	12 (14.3)	4 (14.3)
Redness	0	0	1 (4.2)	0	0	0	0	1 (3.6)
Swelling	1 (4.2)	0	1 (4.2)	0	0	0	1 (1.2)	1 (3.6)
Other reactions	0	0	0	0	0	0	0	0
0-28 d								
Total adverse reactions	5 (20.8)	4 (16.7)	6 (25.0)	3 (12.5)	5 (6.0)	4 (14.3)	16 (19.0)	5 (17.9)

La dosis alta es más reactogénica. La dosis media es similar al placebo

JAMA. doi:10.1001/jama.2020.15543. Published online August 13, 2020

Vacuna Virus Inactivado Sinopharm cepa WIV04 - Inmunogenicidad

Figure 3. Antibody Responses 14 Days After the Second Dose in the Phase 2 Trial



Seroconversiónen 100% en fase 1 y en 0 -21 de fase 2

El esquema 0-21 es más inmunogénico. N: 224 (112 por grupo) Dosis media, Alum 0.5 mg

JAMA. doi:10.1001/jama.2020.15543. Published online August 13, 2020

Vacuna virus inactivado Sinopharm cepa HB02

- Denominación: BBIBP-CorV
- Desarrolada por: Beijing Institute of Biological Products (Beijing, China)
- Aislamiento original de la cepa de SARS-CoV-2 proveniente de HNF y BAL de tres pacientes de 3 hospitales (Wuhan Jinyitan Hospital, Chongqin Wushan County People's Hospital y Qingdao Binhai New District Hospital)
- Cepa seleccionada: 19nCoV-CDC-Tan-HB02 (HB02) por alta replicación en células vero (celulas epiteliales del riñón de un mono africano)
- Inactivación: beta-propionolactona
- Adyuvante: hidróxido de aluminio
- Formulación líquida

***Lancet Infect Dis* 2020.** Published **Online** October 15, 2020 https://doi.org/10.1016/ S1473-3099(20)30831-8

Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBIBP-CorV: a randomised, double-blind, placebo-controlled, phase 1/2 trial

Shengli Xia*, Yuntao Zhang*, Yanxia Wang*, Hui Wang*, Yunkai Yang*, George Fu Gao*, Wenjie Tan*, Guizhen Wu*, Miao Xu*, Zhiyong Lou*, Weijin Huang*, Wenbo Xu*, Baoying Huang*, Huijuan Wang*, Wei Wang, Wei Zhang, Na Li, Zhiqiang Xie, Ling Ding, Wangyang You, Yuxiu Zhao, Xuqin Yang, Yang Liu, Qian Wang, Lili Huang, Yongli Yang, Guangxue Xu, Bojian Luo, Wenling Wang, Peipei Liu, Wanshen Guo, Xiaoming Yang

- Fase 1:
  - grupo 1 (18 – 59 años) (n: 96) – grupo 2 (≥ 60 años hasta 80 años) (n:96)
  - 2 dosis (0 y 28 días), 2 µg, 4 µg, 8 µg vs placebo (SS + OHAl)
- Fase 2:
  - 18 – 59 años (n: 448)
  - Única dosis 8 µg vs placebo
  - 2 dosis (0 y 14 ó 0 y 21 ó 0 y 28 d) vs placebo (1:1:1:1)

Objetivos → Seguridad y tolerabilidad

Objetivos → Inmunogenicidad (Acs neutralizantes)

***Lancet Infect Dis* 2020.** Published **Online** October 15, 2020 https://doi.org/10.1016/ S1473-3099(20)30831-8

Fase 1: Seguridad grupo 18 a 59 años

	2 µg cohort (n=32)			4 µg cohort (n=32)			8 µg cohort (n=32)			Total (n=96)		
	Vaccination (n=24)	Placebo (n=8)	p value	Vaccination (n=24)	Placebo (n=8)	p value	Vaccination (n=24)	Placebo (n=8)	p value	Vaccination (n=72)	Placebo (n=24)	p value
All adverse reactions within 0–7 days												
Any	11 (46%)	3 (38%)	>0·99	8 (33%)	2 (25%)	>0·99	11 (46%)	1 (13%)	0·20	30 (42%)	6 (25%)	0·22
Grade 1	10 (42%)	3 (38%)	..	8 (33%)	2 (25%)	..	11 (46%)	1 (13%)	..	29 (40%)	6 (25%)	..
Grade 2	1 (4%)	0	..	0	0	..	1 (4%)	0	..	2 (3%)	0	..
Injection site adverse reactions within 0–7 days												
Pain	9 (38%)	1 (13%)	0·38	7 (29%)	1 (13%)	0·64	9 (38%)	0	0·07	25 (35%)	2 (8%)	0·017
Grade 1	9 (38%)	1 (13%)	..	7 (29%)	1 (13%)	..	9 (38%)	..	..	25 (35%)	2 (8%)	..
Grade 2	0	0	..	0	0	..	0	0	..	0	0	..
Swelling	0	0	..	0	1 (13%)	0·25	2 (8%)	0	>0·99	2 (3%)	1 (4%)	>0·99
Grade 1	0	0	..	0	1 (13%)	..	1 (4%)	0	..	1 (1%)	1 (4%)	..
Grade 2	0	0	..	0	0	..	1 (4%)	0	..	1 (1%)	0	
Itch	0	0	..	1 (4%)	0	>0·99	0	0	..	1 (1%)	0	>0·99
Grade 1	0	0	..	1 (4%)	0	..	0	0	..	1 (1%)	0	..
Grade 2	0	0	..	0	0	..	0	0	..	0	0	..
Redness	1 (4%)	0	>0·99	0	0	..	0	0	..	1 (1%)	0	>0·99
Grade 1	1 (4%)	0	..	0	0	..	0	0	..	1 (1%)	0	..
Grade 2	0	0	..	0	0	..	0	0	..	0	0	..
Systemic adverse reactions within 0–7 days												
Fever	1 (4%)	2 (25%)	0·15	1 (4%)	0	>0·99	2 (8%)	0	>0·99	4 (6%)	2 (8%)	0·64
Grade 1	1 (4%)	2 (25%)	..	1 (4%)	0	..	2 (8%)	0	..	4 (6%)	2 (8%)	..
Grade 2	0	0	..	0	0	..	0	0	..	0	0	..

Fase 1: Seguridad grupo ≥ 60 años

	2 µg cohort (n=32)			4 µg cohort (n=32)			8 µg cohort (n=32)			Total (n=96)		
	Vaccination (n=24)	Placebo (n=8)	p value	Vaccination (n=24)	Placebo (n=8)	p value	Vaccination (n=24)	Placebo (n=8)	p value	Vaccination (n=24)	Placebo (n=8)	p value
All adverse reactions within 0–7 days												
Any	1 (4%)	1 (13%)	0·44	6 (25%)	0	0·30	5 (21%)	1 (13%)	>0·99	12 (17%)	2 (8%)	0·51
Grade 1	1 (4%)	1 (13%)	..	6 (25%)	0	..	4 (17%)	1 (13%)	..	11 (15%)	2 (8%)	..
Grade 2	0	0	..	0	0	..	1 (4%)	0	..	1 (1%)	0	..
Injection site adverse reactions within 0–7 days												
Pain	1 (4%)	1 (13%)	0·44	4 (17%)	0	0·55	4 (17%)	0	0·55	9 (13%)	1 (4%)	0·44
Grade 1	1 (4%)	1 (13%)	..	4 (17%)	0	..	4 (17%)	0	..	9 (13%)	1 (4%)	..
Grade 2	0	0	..	0	0	..	0	0	..	0	0	..
Induration	0	0	..	0	0	..	2 (8%)	0	>0·99	2 (3%)	0	>0·99
Grade 1	0	0	..	0	0	..	1 (4%)	0	..	1 (1%)	0	..
Grade 2	0	0	..	0	0	..	1 (4%)	0	..	1 (1%)	0	..
Systemic adverse reactions within 0–7 days												
Fever	0	0	..	0	0	..	1 (4%)	0	>0·99	1 (1%)	0	>0·99
Grade 1	0	0	..	0	0	..	1 (4%)	0	..	1 (1%)	0	..
Grade 2	0	0	..	0	0	..	0	0	..	0	0	..

Fase 1: Inmunogenicidad grupo 18 a 59 años y ≥ 60 años

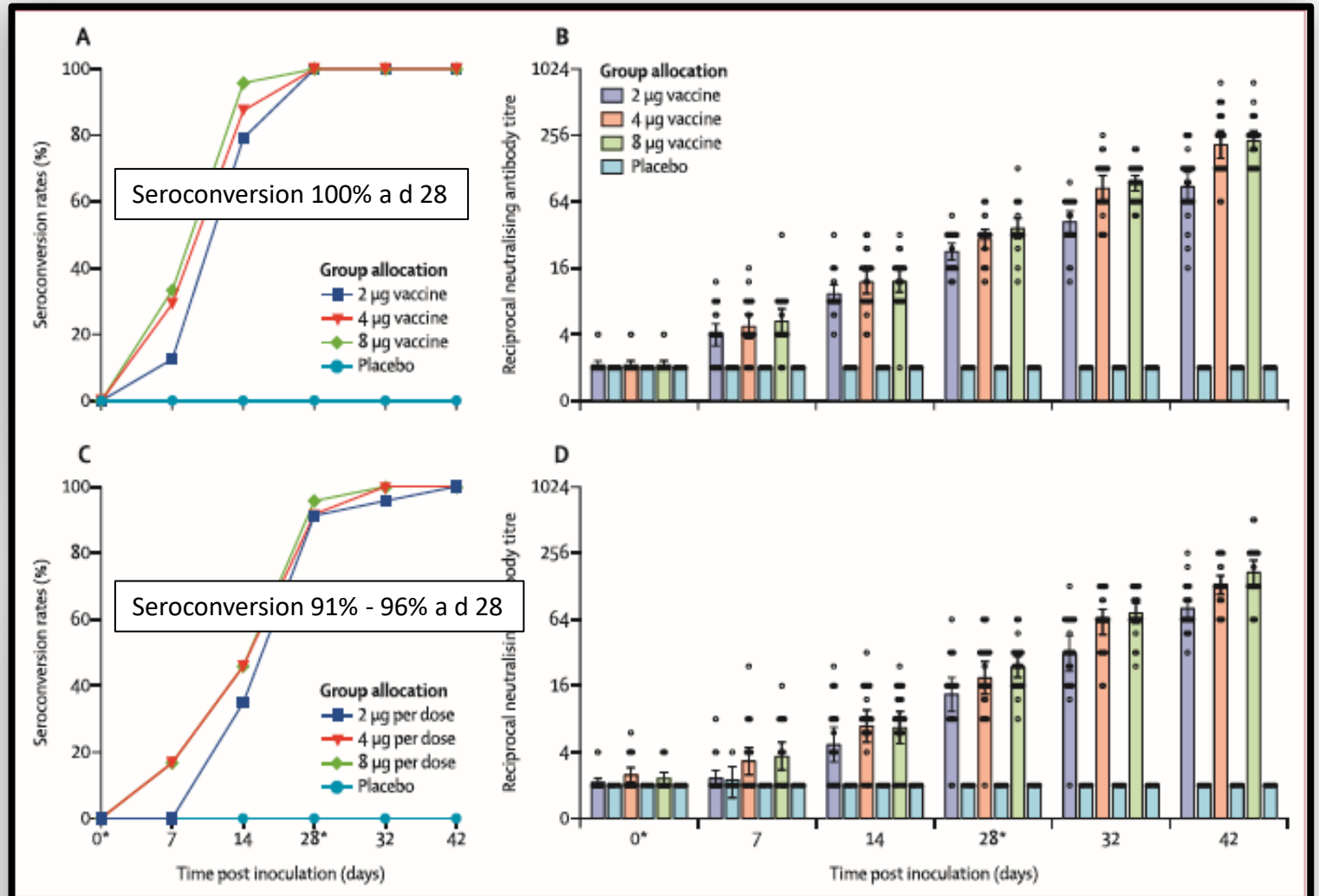


Figure 2: Seroconversion ratios and neutralising antibody titres for and 60 years and older
Seroconversion rates (A) and neutralising antibody titres (B) for participants aged 18–59 years; and seroconversion rates (C) and neutralising antibody titres (D) for participants aged 60 years and older. We defined the seroconversion as at least a four-fold increase in post-vaccination titre from baseline. The negative in neutralisation antibody detection is represented as a GMT of 2. *Days of vaccination.

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Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBIBP-CorV: a randomised, double-blind, placebo-controlled, phase 1/2 trial

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- Fase 2: (n: 448)
  - SEGURIDAD:
    - 23% algún evento adverso en primero 7 días (más frecuente con dosis 8 µg)
    - Todas reacciones leves a moderadas
    - Reacciones sistémicas: fiebre más frecuente (1% a 4%)
  - INMUNOGENICIDAD (GMT):
    - Mayores títulos de Acs neutralizantes con dosis de 4 µg (0 y 14 d ó 0 y 21 d ó 0 y 28 d) que con DU de 8 µg
    - 4 µg d 0 y 14 d (169.5, 95% IC 132.2–217.1)
    - 4 µg d 0 y 21 d (282.7, 221·2–361.4)
    - 4 µg d 0 y 28 (218.0, 181.8–261.3)
    - 8 µg d 0 (14.7, 11.6–18.8)
    - Todos los casos p<0·001 comparado con 8 µg d 0

***Lancet Infect Dis* 2020.** Published **Online** October 15, 2020 https://doi.org/10.1016/ S1473-3099(20)30831-8

Ensayos clínicos en desarrollo

Argentina

- Ensayo clínico de fase III, aleatorizado, de doble enmascaramiento, controlado con placebo, en grupos paralelos para evaluar la eficacia, inmunogenicidad y la seguridad de la vacuna inactivada contra el SARS-CoV-2 en una población sana entre los 18 años y los 85 años de edad. (LABORATORIO ELEA PHOENIX S A – Sinopharm) NCT04560881
- Investigador Coordinador: Dr Pedro Cahn, Fundación Huésped
- Investigadores Principales: Dra Florencia Cahn, Dr Pablo Bonvehí y Dr Ricardo Rüttimann, Fundación Vacunar

https://www.argentina.gob.ar/anmat/regulados/investigaciones-clinicas-farmacologicas/Estudios-autorizados-COVID19

Clinical Trial to Evaluate the Efficacy, Immunogenicity and Safety of the Inactivated SARS-CoV-2 Vaccine (COVID-19)

ClinicalTrials.gov Identifier: NCT04560881

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

Recruitment Status : Active, not recruiting
First Posted : September 23, 2020
Last Update Posted : November 27, 2020

Sponsor:

Laboratorio Elea Phoenix S.A.

Collaborators:

Beijing Institute of Biological Products Co., Ltd
China National Biotec Group Company Limited
Fundación Huésped

Information provided by (Responsible Party):

Laboratorio Elea Phoenix S.A.

Study Design

Go to

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	3000 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	Clinical trial conducted in randomized, double-blinded, placebo-controlled design.
Masking:	Triple (Participant, Care Provider, Investigator)
Primary Purpose:	Prevention
Official Title:	Randomized, Double Blind, Placebo Parallel-controlled Phase III Clinical Trial to Evaluate the Efficacy, Immunogenicity and Safety of the Inactivated SARS-CoV-2 Vaccine (Vero Cell) in Argentine Healthy Population Aged Between 18 and 85 Years
Actual Study Start Date :	September 16, 2020
Estimated Primary Completion Date :	December 1, 2021
Estimated Study Completion Date :	December 1, 2021

Arms and Interventions

Go to

Arm	Intervention/treatment
Experimental: Inactivated SARS-CoV-2 vaccine, manufactured by BIBP Intramuscular injection	Biological: Inactivated SARS-CoV-2 vaccine (Vero cell) Immunization schedule: 2-doses of investigational vaccine or placebo are inoculated to the deltoid muscle of the upper arm according to the immunization schedule of Day 0, 21.
Placebo Comparator: Placeboof Inactivated SARS-CoV-2 vaccine, manufactured by BIBP Intramuscular injection	Biological: Placebo/Aluminum Adjuvant of Inactivated SARS-CoV-2 vaccine Immunization schedule: 2-doses of investigational vaccine or placebo are inoculated to the deltoid muscle of the upper arm according to the immunization schedule of Day 0, 21.

Outcome Measures

Go to

Primary Outcome Measures :

1. Incidence of COVID-19 cases after two-doses of vaccination [Time Frame: 14 days after the full course of vaccination]

   All confirmed COVID -19 cases 14 days after the full course of vaccination among healthy population aged between 18 and 85 years old.

Secondary Outcome Measures :

1. The 4-fold increase rate of anti-SARS-CoV-2 neutralizing antibody [Time Frame: 14 days after 2-dose of immunization and 28 days after full course of immunization]
2. The Geometric Mean Titer (GMT) of anti-SARS-CoV-2 neutralizing antibody [Time Frame: 14 days after 2-dose of immunization and 28 days after full course of immunization]
3. The Geometric Mean Increase (GMI) of anti-SARS-CoV-2 neutralizing antibody [Time Frame: 14 days after 2-dose of immunization and 28 days after full course of immunization]
4. Incidence of any adverse reactions/events [Time Frame: Within 30 minutes after each dose of vaccine]
5. Incidence of adverse reactions/events [Time Frame: 0 ~ 21/28 days after each dose of vaccine]
6. Incidence of serious adverse events (SAE) [Time Frame: From the beginning of the first dose to 12 months after the whole course of immunization]

Other Outcome Measures:

1. Anti-SARS-CoV-2 neutralizing antobody (NtAb) (immunological surrogate endpoint) [Time Frame: 14 days after 2-dose of immunization.]

   The protective level of Anti-SARS-CoV-2 NtAbs

Eligibility Criteria

Go to

Information from the National Library of Medicine

NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years to 85 Years (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

- Healthy subjects aged between 18 and 85 years old.
- By asking for medical history and physical examination, the investigator judged that the health condition is well.
- Female subjects of childbearing age are not nursing or pregnant at the time of enrolment (negative urine pregnancy test) and have no family planning within the first 3 months after enrolment. Effective contraceptive measures have been taken within 2 weeks before inclusion.
- During the whole follow-up period of the study, be able and willing to complete the whole prescribed study plan.
- With self-ability to understand the study procedures, the informed consent & voluntarily sign an informed consent form and be able to comply with the requirements of the protocol.

Exclusion Criteria:

- Active Sars-Cov-2 Infection measured by RT-qPCR
- Has a history of SARS, MERS infection (self-report, on-site inquiry)
- Has clinical manifestation of fever (axillary temperature > 37.0 °C), dry cough, fatigue, nasal obstruction, runny nose, pharyngeal pain, myalgia, diarrhea, shortness of breath and dyspnea occurred within 14 days before vaccination.
- Body temperature > 37.0 °C before vaccination
- Urine pregnancy test positive;
- Previous severe allergic reactions to vaccination (such as acute allergic reactions, urticaria, dyspnea, angioneurotic edema or abdominal pain) or allergy to known ingredients of inactivated SARS-CoV-2 vaccine have occurred.
- Has a history of convulsion, epilepsy, encephalopathy or mental illness or family history.
- With congenital malformations or developmental disorders, genetic defects, severe malnutrition, etc.
- With severe liver and kidney diseases, uncontrollable hypertension (systolic blood pressure ≥ 140 mmHg, diastolic blood pressure ≥ 90 mmHg), diabetic complications, malignant tumors, various acute diseases, or acute attack period of chronic diseases.
- Has been diagnosed with congenital or acquired immune deficiency, HIV infection, lymphoma, leukemia, or other autoimmune diseases.
- With known or suspected diseases include severe respiratory diseases, severe cardiovascular diseases, liver and kidney diseases, and malignant tumors.
- Has a history of coagulation dysfunction (e.g. Coagulation factor deficiency, coagulation disease)
- Receiving anti-TB therapy.
- Patients receiving immunotherapy or inhibitor therapy within 3 months (continuous oral or infusion for more than 14 days)
- Inoculated live attenuated vaccines within 1 month before this vaccination, other vaccines are inoculated within 14 days before this vaccination.
- Received blood products within 3 months before this vaccination
- Received other research drugs within 6 months before this vaccination.
- Other circumstances judged by investigators that are not suitable for this clinical trial.

https://clinicaltrials.gov/ct2/show/NCT04560881

Locations

Argentina

Fundación Huésped

Ciudad Autónoma de Buenos Aires, Buenos Aires, Argentina, C1202ABB

Vacunar Liniers

Ciudad Autónoma de Buenos Aires, Buenos Aires, Argentina, C1408FVD

Vacunar Cañitas

Ciudad Autónoma de Buenos Aires, Buenos Aires, Argentina, C1426BOF

Vacunar Coghlan

Ciudad Autónoma de Buenos Aires, Buenos Aires, Argentina, C1430BKB

Sponsors and Collaborators

Laboratorio Elea Phoenix S.A.

Beijing Institute of Biological Products Co., Ltd

China National Biotec Group Company Limited

Fundación Huésped

More Information

Responsible Party:	Laboratorio Elea Phoenix S.A.
ClinicalTrials.gov Identifier:	NCT04560881 History of Changes
Other Study ID Numbers:	BIBP2020003AR
First Posted:	September 23, 2020 Key Record Dates
Last Update Posted:	November 27, 2020

https://clinicaltrials.gov/ct2/show/NCT04560881

Ensayos clínicos/sitios/voluntarios

- Emiratos Arabes Unidos: 31.000
- Marruecos: 600
- Egipto: 6000
- Bahrein: 7700
- Jordania: 500
- Pakistán: 3000
- Perú: 12.000

TOTAL: 60.800 + 3000 (Argentina) = 63.000 voluntarios

Datos de eficacia de fase 3 informados

El Ministerio de Salud y Prevención de Emiratos Árabes Unidos (EAU) dijo este miércoles que ha registrado la vacuna para el coronavirus desarrollada por la farmacéutica Sinopharm y el Instituto de Productos Biológicos de Beijing, y anunció que ha demostrado una "eficacia del 86%" contra el COVID-19, informó la agencia estatal emirati WAM. Según los análisis, **presenta "una tasa del 99% de seroconversión de anticuerpos neutralizantes" y "100% de efectividad en la prevención de casos moderados y severos de la enfermedad"**.

Por otro lado, se informó que los análisis **no han mostrado problemas serios de seguridad en la vacuna**, que empezó sus ensayos clínicos de la fase 3 en julio. Dicha instancia incluyó a 31.000 voluntarios de 125 nacionalidades solo en Emiratos.

El Ministerio de Salud y Prevención de los Emiratos Árabes Unidos (MOHAP) anuncia el registro oficial de la vacuna del COVID-19 inactivado del Instituto de Productos Biológicos de Beijing

Sinopharm desarrolla dos vacunas distintas, ambas de virus inactivo: **una con el Instituto de Productos Biológicos de Wuhan y otra con el con el Instituto de Productos Biológicos de Beijing.** Estas dos vacunas de Sinopharm se han estado utilizando en China en casos especiales desde el pasado agosto, principalmente entre personal sanitario y militar, así como diplomáticos empleados en el extranjero, que ya han recibido su dosis.

(REUTERS/Tingshu Wang) 24 Dic 2020

By Sui-Lee Wee and Amy Qin

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The Chinese government said on Thursday that it had approved a homegrown coronavirus vaccine after an early analysis of clinical trial results showed that it was effective. The announcements sent a positive signal for the global rollout of Chinese vaccines but lacked crucial details.

The manufacturer, a state-controlled firm called Sinopharm, said on Wednesday that a vaccine candidate made by its Beijing Institute of Biological Products arm had an efficacy rate of 79 percent based on an interim analysis of Phase 3 trials. Sinopharm said it had filed an application with Chinese regulators to allow the vaccine to be used broadly, and on Thursday the government said the vaccine had been granted conditional approval.

Sinopharm-WIV04 (Wuhan)

Wuhan Inst of Biol Products informó 72,5% de eficacia. *24 Feb 2021*

https://www.nytimes.com/2020/12/30/business/china-vaccine.html

Aprobación vacuna Sinopharm

Sinopharm: países donde se aprobó la vacuna

- Asia:
  - Bahrein, Camboya, China, Irán, Iraq, Jordania, Nepal, Pakistán, Emiratos Arabes Unidos
- Africa:
  - Egipto, Marruecos
- Sudamérica:
  - Argentina, Perú, Bolivia
- Europa:
  - Serbia, Hungría

https://en.wikipedia.org/wiki/BBIBP-CorV

Sinopharm: Manual del Vacunador Argentina

Dirección de
Control de Enfermedades
Inmunoprevenibles

Ministerio de Salud
Argentina

28 de Febrero de 2021

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2. Eficacia

Los resultados preliminares del ensayo clínico de Fase III mostraron que después de 14 días de vacunación con un esquema de dos dosis la eficacia contra la COVID-19 fue del 79,34% (IC 95%: 59,17% -89,55%).

3. Aspectos regulatorios:

El 21 de febrero de 2021 fue publicada la Resolución Ministerial 688/2021 del Ministerio de Salud de la Nación, donde consta que la Administración Nacional de Medicamentos, Alimentos y Tecnología (ANMAT) ha intervenido en el marco de sus competencias y ha recomendando la autorización de la vacuna SINOPHARM, vacuna SARS-CoV-2 (células vero) inactivada, para su uso en situaciones de emergencia en mayores de 18 años y hasta 59 años (inclusive).

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1. Composición y características de la vacuna

Vacuna contra la COVID-19 SINOPHARM® utiliza una plataforma de virus inactivado en cultivos de células VERO.

Composición y características:

Principio activo: antígenos del virus SARS-CoV-2 inactivado, en una cantidad de 6,5 U/dosis

Adyuvante: hidróxido de aluminio en cantidad de 0,225 mg/dosis

Excipientes: fosfato de hidrógeno disódico 1,4 mg/dosis; fosfato de di-hidrógeno de sodio 0,1373 mg/dosis; cloruro de sodio 4,25 mg/dosis.

Descripción: Solución semitransparente, ligeramente blanquecina y libre de partículas; puede presentar un sedimento por precipitación que se puede dispersar fácilmente mediante la agitación suave del vial previo a la aplicación de la vacuna; pH 6,6-7,6.

Duración bajo conservación a 2 - 8°C : 24 meses

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2. Forma farmacéutica y conservación

Forma farmacéutica de presentación de SINOPHARM:

Solución para inyección intramuscular, lista para su uso. Se presenta en un vial monodosis:

- Vial con **0,5 mL** de solución que corresponde a **1 dosis de vacuna**
- **Embalajes:** 1 vial monodosis por caja o 3 viales monodosis por caja.

Condiciones de conservación:

a. Condiciones de conservación para el vial cerrado:

- El vial debe conservarse a temperaturas de refrigeración (2 a 8°C)
- **No congelar**
- Proteger de la luz

b. Una vez abierto el vial monodosis:

- Se recomienda aplicar el contenido **de forma inmediata una vez abierto el vial**
- Se debe desechar cualquier vial abierto cuyo contenido no haya sido utilizado al momento de su apertura

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3. Dosis y vía de administración

Dosis: 0,5 mL.

Número de dosis requeridas: 2 (dos)

Vía de administración: intramuscular.

Sitio de aplicación: músculo deltoides (el tercio superior externo del hombro externo).

El calibre de la aguja para esta ubicación de inyección puede estar entre 22G y 25G o entre 5/8 y 1 pulgada, según la técnica de administración.

5. Esquemas de vacunación

ESQUEMA DE VACUNACIÓN CON LA VACUNA SINOPHARM	
Número de dosis	2 (dos) de aplicación intramuscular
Intervalo mínimo entre dosis:	21a 28 días (3 a 4 semanas)
Intercambiabilidad	Las personas que inician una serie con la vacuna SINOPHARM deben completar la serie con el mismo producto. No hay datos que avalen la intercambiabilidad entre las distintas vacunas disponibles contra la COVID-19.

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7. Eventos adversos

Los eventos adversos (EA) característicos identificados, así como en estudios de otras vacunas contra la COVID-19, son principalmente leves o moderados y resuelven en su totalidad a los pocos días de la vacunación.

Más frecuentes:

Locales:

- **Muy frecuente (>10%):** dolor en el sitio de la inyección
- **Frecuentes (1-10%):** eritema, hiperemia, prurito, edema y/o hinchazón en el sitio de la inyección
- **Poco frecuentes (<1%):** rash cutáneo en el sitio de la inyección

Generales:

- **Frecuentes (1-10%):** fatiga, fiebre transitoria, cefalea, diarrea, tos, disnea.
- **Poco frecuentes (<1%):** náuseas, vómitos, mialgias, artralgias, somnolencia, mareos, anorexia.

Se recomienda el uso de AINEs/paracetamol ante la aparición de fiebre después de la vacunación.

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8. Contraindicaciones y precauciones

Contraindicaciones:

- Hipersensibilidad a cualquier componente de una vacuna o a una vacuna que contenga componentes similares.
  - **Contraindicación para la 2º dosis:** reacción anafiláctica con la primera dosis.
- Antecedente de reacciones alérgicas graves (con compromiso respiratorio que haya requerido asistencia médica).
- Exacerbación de enfermedades crónicas, que impliquen compromiso del estado general.

Precauciones:

- **Enfermedad febril aguda grave** (con compromiso del estado general): Al igual que con otras vacunas, la administración de la vacuna SINOPHARM debe posponerse en personas que padecen una enfermedad febril aguda grave.

- **Trombocitopenia y trastornos de la coagulación**: Al igual que con otras inyecciones intramusculares, la vacuna SINOPHARM debe administrarse con precaución en personas con trombocitopenia o cualquier trastorno de la coagulación dado que pueden ocurrir hemorragias o hematomas post inyección.
- **Epilepsia no controlada u otro trastorno neurológico progresivo**

Características de la Vacuna SINOPHARM

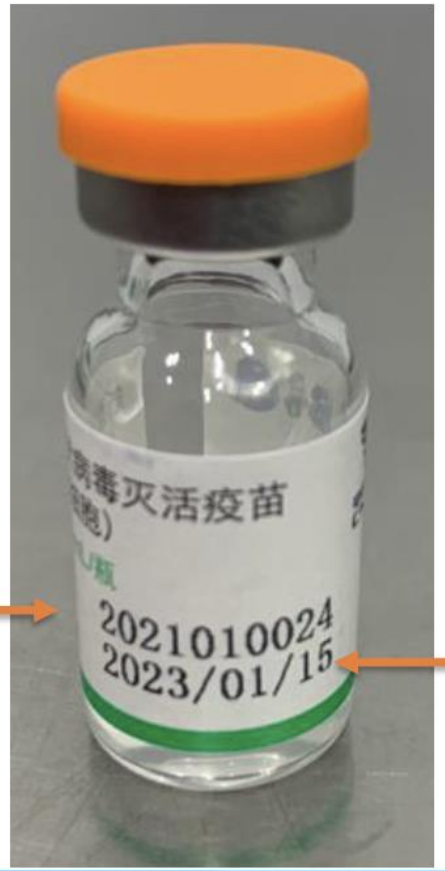
Solución para la aplicación intramuscular (IM) en región deltoides

Contiene **0,5 mL** para vacunar a 1 persona **(1 dosis).**

La información referida a número de lote permite la trazabilidad del biológico

0,5 mL

1 DOSIS



Número de LOTE

Fecha de vencimiento

Conclusiones

- Las vacunas inactivadas contra SARS-CoV-2 producidas por Sinopharm han demostrado ser inmunogénicas y seguras en fases iniciales
- Los virus candidatos se cultivan en células Vero, e inactivan con beta-propionolactona y utilizan Hidróxido de Aluminio como adyuvante
- Se almacenan entre 2 - 8 ºC
- Requieren 2 dosis
- Resultados de eficacia aún no publicados, informan que la misma sería 79% para prevenir enfermedad y >90% para las formas graves
- En Argentina se destinará inicialmente a adultos de 18 a 59 años, administrando 2 dosis de 0,5 ml con un intervalo de 21 a 28 días

Muchas Gracias