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A study to see if a new 6-in-1 (hexavalent) vaccine is effective and safe for babies in countries with polio

Submission date
26/11/2025

Recruitment status
Not yet recruiting

Registration date
13/01/2026

Overall study status
Ongoing

Last Edited
26/01/2026

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Polio is still present in Pakistan, and children are vaccinated using two types of polio vaccines: OPV (oral polio vaccine) and IPV (injected polio vaccine). Currently, babies receive several separate injections for different diseases. A new vaccine called Hexavalent (Hexasiil) combines protection against six illnesses—diphtheria, tetanus, whooping cough, hepatitis B, Hib, and polio—into one shot. This study will check if the Hexavalent vaccine works as well as the current schedule of Pentavalent (five-in-one) plus IPV for protecting against polio. Researchers will also look at whether giving four doses of Hexavalent makes a difference.

Who can participate?
Healthy babies who were born full-term (at least 37 weeks), are 6–8 weeks old when joining the study, live in the study area for at least 3 months, and have parents or guardians who agree to take part. Babies cannot join if they are very ill, severely underweight, have immune problems, certain medical conditions, or allergies to vaccine ingredients.

What does the study involve?
Babies will be randomly placed into one of four groups. Each group gets a different vaccination schedule using either the Hexavalent vaccine or the current Pentavalent plus IPV schedule. Vaccines will be given at either 6, 10, and 14 weeks or at 2, 4, and 6 months. Parents will bring their baby for blood tests at the start and at several points until the baby is 9 months old. These tests check how well the vaccines worked. After each vaccination, babies will be observed for 30 minutes and parents will record any side effects for 28 days.

What are the possible benefits and risks of participating?
Benefits include babies receiving WHO-approved vaccines under close medical care, parents learning more about vaccination and follow-up care, and the study helping improve Pakistan’s immunization program. Risks include common side effects like pain, swelling, redness, or fever, and rare but serious allergic reactions. If any serious problems occur, the study team will act quickly and may stop further vaccinations. Safety is monitored by an independent committee.

Where is the study run from?
The study is led by the Clinical Trial Unit at Aga Khan University Hospital in Karachi, Pakistan. Recruitment happens in Cattle Colony, Ibrahim Hyderi, and Aga Khan Hospital for Women and Children in Kharadar.

When is the study starting and how long is it expected to run for?
The study will run for about 24 months. This includes time for approvals, training, recruitment, vaccinations, follow-up, and analysis. The exact start date depends on ethics approval.

Who is funding the study?
Funding is requested from the WHO Global Polio Eradication Initiative (GPEI) – Polio Research Committee.

Who is the main contact?
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Additional identifiers

Protocol serial number
10032025

Study information

Scientific Title
Randomized trial to evaluate and compare the immunogenicity and safety of hexavalent vaccine in healthy infants in a polio-endemic country

Study objectives
Primary objectives:
1. To compare the humoral immunity against type 1-3 poliovirus after administering 3 doses of the Hexavalent schedule (Arm A) and compare it with the national EPI schedule of pentavalent + IPV administered at 6, 10, and 14 weeks of age (Arm B)
2. To compare the humoral immunity against type 1-3 poliovirus after administering 3 doses of the Hexavalent schedule (Arm C) and compare it with routine immunization pentavalent + IPV administered at 2, 4, and 6 months of age (Arm D)
3. To compare the humoral immunity against type 1-3 poliovirus after administering 4 doses of the Hexavalent schedule given according to the national EPI schedule at 6, 10, 14 weeks, and 9 months of age (Group I) with Hexavalent doses given at 2, 4, 6, and 12 months of age (Group II)
Secondary objectives:
1. To evaluate the humoral immunity against type 1-3 poliovirus after administering the Hexavalent vaccine schedule at 6, 10, and 14 weeks (Arm A) and 2, 4, and 6-month schedule (Arm C)

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/03/2025, Aga Khan University Ethical Review Committee (Stadium Road, P. O. Box 3500, Karachi, 74800, Pakistan; +92 21 3493 0051 Ext: 2447/4988; erc.pakistan@aku.edu), ref: 2025-10964-33978

Study design
Open label- randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Polio virus

Interventions
This is a randomized, open-label, controlled clinical trial designed to evaluate and compare the immunogenicity and safety of a newly prequalified hexavalent vaccine (Hexasiil®, Serum Institute of India) with the currently used pentavalent plus inactivated polio vaccine (IPV) under Pakistan's national immunization schedule. Healthy full-term infants aged 6–8 weeks will be enrolled from peri-urban communities of Karachi and the Aga Khan Hospital for Women and Children, Kharadar. A total of 1,760 infants will be randomized equally into four parallel arms using stratified blocked randomization.

Infants starting at six weeks (Group I) will receive either Hexavalent + OPV or Pentavalent + OPV + IPV according to the national EPI schedule, while those starting at two months (Group II) will receive the same vaccines at 2, 4 and 6 months. The hexavalent vaccine (0.5 mL intramuscularly) contains diphtheria, tetanus, whole-cell pertussis, hepatitis B, Haemophilus influenzae type b, and inactivated poliovirus types 1–3. The comparator pentavalent vaccine contains DTP, Hep B and Hib, administered with separate IPV doses.

Blood samples will be collected at baseline and 28 days after each vaccination for antibody assessment. Safety will be monitored through active follow-up, 30-minute post-vaccination observation, and diary-based adverse-event reporting. An independent Data Safety Monitoring Board will oversee participant safety throughout the study.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hexasiil

Primary outcome(s)
The proportion of infants achieving seroprotection against poliovirus types 1, 2, and 3, measured using blood samples will be for antibody assessment at 4 weeks after the third dose

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The proportion of infants achieving seroprotection against poliovirus types 1, 2, and 3, measured using blood samples will be for antibody assessment at 4 weeks after the fourth (booster) dose

Key secondary outcome(s))
The proportion of infants achieving seroprotection against poliovirus types 1, 2, and 3, measured 4 using blood samples will be for antibody assessment at weeks after the third dose of the Hexavalent vaccine

Completion date
01/01/2027

Eligibility

Key inclusion criteria
1. All healthy full-term infants (born at 37 weeks) at 6-8 weeks old of either gender
2. Not planning to travel away during entire the study period (enrolment- approximately 294 days; 5 weeks – 42 weeks)
3. Parents resident of the study area for the last 3 months at the time of enrolment
4. Parent/guardian provides informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Child

Lower age limit
6 weeks

Upper age limit
8 weeks

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Newborns found acutely ill at the time of enrolment and requiring emergent medical care /hospitalization.
2. Enrolment weight & height <-3 weight for height z-score
3. Infants with certain medical conditions i.e., syndromic infants, infants with petechial, purpura, or bleeding disorder (contraindication of intramuscular injections)
4. A diagnosis or suspicion of immunodeficiency disorder (either in the participant or in a

member of the immediate family - e.g. several early infant deaths, a household member on chemotherapy) will render the newborn ineligible for the study
5. Diagnosed neurological disorder or a history of seizures or temperature >380C in last 3 days or any other indication of acute illness/infection within the past 7 days
6. Having a record of anaphylaxis or allergy to vaccine components

Date of first enrolment
01/03/2026

Date of final enrolment
01/09/2026

Locations

Countries of recruitment
Pakistan

Study participating centre
Clinical Trials Unit- Aga Khan University Hospital
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Sponsor information

Organisation
Aga Khan University Hospital

ROR
https://ror.org/05xcx0k58

Funder(s)

Funder type
Not defined

Funder Name
World Health Organization

Alternative Name(s)

, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type
Government organisation

Funding Body Subtype
International organizations

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study wil lbe available upon request from Ali Faisal Saleem ali.saleem@aku.edu

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	14/12/2024	01/12/2025	No	No