ISRCTN66014475 https://doi.org/10.1186/ISRCTN66014475

European preparedness platform to treat and prevent respiratory syncytial virus infections in pregnant women and infants

Submission date
16/07/2025

Recruitment status
Recruiting

Registration date
19/09/2025

Overall study status
Ongoing

Last Edited
19/09/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
In recent years, there have been outbreaks of new or re-emerging infections, such as the Zika virus and COVID-19. Pregnant women and infants are at risk of serious health problems from some of these infections. Despite this, these populations are often excluded from research studies, meaning that it is unclear whether new vaccines and treatments are safe and work well for them. The purpose of PIPELINE is to provide a European preparedness platform for clinical trials and observational studies to treat and prevent infections in pregnant women and infants. Studies conducted within the PIPELINE platform will allow dedicated studies in pregnant women and infants to happen more quickly, resulting in equal access to new medicines as they become available. The PIPELINE-RSV International Trial will test the platform by running a multi-country trial, focusing on preventing a common respiratory infection called RSV in infants. Currently, two different medicines can be used to prevent RSV infection in babies: one is a vaccine given to the mother during pregnancy, and the other is an injection given to the baby. It is not known whether giving one or the other, or both medicines together, would provide the best protection.

Who can participate?
Pregnant women aged 18 years or older, between 28+0 and 36+6 weeks' gestational age, will be enrolled into the study.

What does the study involve?
In the UK, the study will have two different groups: group 1 – a vaccine to the mother in pregnancy OR group 2 – both a vaccine to the mother in pregnancy and an injection to the baby at 4 months. Participants will be followed up until the baby reaches 12 months of age. Visits with the mother and baby will occur at birth, 4 months, and 12 months, and a swab will be taken from the baby's nose if they show possible signs of RSV infection.

What are the possible benefits and risks of participating?
Participants will receive a medicine that can help prevent serious illness from RSV in both the

mother and their baby. Families in the study will get extra health checks and support. This study will also help doctors and health leaders find the best ways to prevent RSV. This could mean fewer doctor visits, fewer hospital stays, and less pressure on healthcare services.

Participants in the PIPELINE-RSV International Trial will either receive the maternal vaccine or the infant monoclonal antibody. There is always a very small risk of an adverse reaction following vaccination, and this will be explained to participants, but this risk is not greater for women in this study compared to those who receive the vaccine as part of routine care. Vaccines are anticipated to cause a range of local and systemic adverse events and these may include pain, swelling and tenderness at the injection site as well as headache, myalgia, nausea and fever.

For infants receiving the monoclonal antibodies, the risks and side effects are usually mild and resolve on their own and again, are not greater for infants in this study compared to those who receive the monoclonal antibody as part of routine care in many countries. It is generally well tolerated, but the injection may cause some pain, redness, swelling and may result in fever and a rash. There may be participant burden associated with the requirement to attend additional visits or complete questionnaires, and this should be minimised through alignment with routine care visits where possible. There may also be risks, including pain or discomfort, associated with nasopharyngeal swab collection.

Where is the study run from?
PENTA Foundation, Italy

When is the study starting and how long is it expected to run for?
July 2025 to March 2029

Who is funding the study?
European Health and Digital Executive Agency (HaDEA), European Commission

Who is the main contact?
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Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1012051

ClinicalTrials.gov (NCT)
NCT07041190

Protocol serial number
Nil known

Study information

Scientific Title
Pregnancy and Infant PrEparedness pLatform IN Europe (PIPELINE)- RSV immunisation adaptive platform trial

Acronym
PIPELINE-RSV International Trial

Study objectives
1. To determine if the administration of year-round MV (administered between 24+0 and 36+6 weeks of gestation) plus infant mAb administered at 4 months of age provides superior protection against symptomatic RSV infection in infants by 12 months of age compared with infant mAb administered in the first RSV season following birth.
2. To determine if the administration of year-round MV (administered between 24+0 and 36+6 weeks of gestation) plus infant mAb administered at 4 months of age provides superior protection against symptomatic RSV infection in infants by 12 months of age compared with year-round MV in pregnancy.

The first secondary objective is to rank the single interventions, year-round MV in pregnancy and infant mAb administered in the first RSV season following birth, with respect to prevention of symptomatic RSV infection in infants by 12 months of age, and to estimate the difference between them in terms of efficacy.

Further secondary objectives are to evaluate the interventions based on secondary efficacy and safety outcomes listed below, as well as on measures of acceptability of interventions and cost-effectiveness.
Exploratory objectives will explore the impacts of seasonality, timing of maternal vaccine, gestation age at birth and co-administration of other maternal vaccines on efficacy of the interventions.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/09/2025, - (-, -, -, United Kingdom; -; -), ref: 25/SC/0251

Study design
Randomized controlled open-label parallel-group study

Primary study design
Interventional

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Respiratory syncytial virus (RSV) in infants

Interventions
• Active Comparator: Seasonal RSV monoclonal antibody administered to infants at birth (or up to 7 days later) if the infant is born during the RSV season. Nirsevimab, Infant RSV monoclonal antibody (mAb). For infants <5kg: 50mg (0.5mL in pre-filled syringe), for infants ≥5kg: 100mg (1mL in pre-filled syringe), administered as a single intramuscular injection.
• Active Comparator: RSV Maternal Vaccine administered to the woman in pregnancy, between 24 (or as per country guidance) and 36+6 gestational weeks. Abrysvo, Maternal RSV Vaccine (MV). RSV bivalent recombinant vaccine with subgroup A and B stabilised prefusion F antigens, single intramuscular injection of 0.5 mL, administered once, in pregnancy.
• Experimental: RSV Maternal Vaccine + RSV infant monoclonal antibody at 4months of age. RSV Maternal Vaccine administered to the woman in pregnancy, between 24 (or as per country guidance) and 36+6 gestational weeks, combined with infant RSV monoclonal antibody administered to the infant at 4 months of age. Abrysvo, a single intramuscular injection of 0.5 mL, administered once, in pregnancy and Nirsevimab, for infants <5kg: 50mg (0.5mL in pre-filled syringe), for infants ≥5kg: 100mg (1mL in pre-filled syringe), administered as a single intramuscular injection.

Randomisation: Parallel assignment

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)

RSV subgroup A stabilised prefusion F antigen, RSV subgroup B stabilised prefusion F antigen, Nirsevimab

Primary outcome(s)
Symptomatic RSV respiratory tract infection (RTI) in an infant, confirmed by an approved positive RSV test, from birth to when the infant is 12 months of age.

Key secondary outcome(s))
Infants:
1. RSV RTI by 3 and 6 months of age
2. Medically-attended (MA)-RSV RTI by 3, 6 and 12 months of age
3. RSV RTI-associated hospitalisations by 3, 6 and 12 months of age
4. RSV RTI with SpO2
5. RSV RTI-associated deaths by 12 months of age
6. All-cause RTI by 3, 6 and 12 months of age
7. All-cause MA-RTI by 3, 6 and 12 months of age
8. All-cause RTI-associated hospitalisations by 3, 6 and 12 months of age
9. All-cause RTI with SpO2
10. All-cause RTI-associated deaths by 12 months of age
11. MA-wheezing with 1 or more episodes by 12 months
12. Cycle threshold (Ct) value overall and by RSV subtype (RSV-A or RSV-B) for RSV-infection confirmed by reverse transcription polymerase chain reaction (RT-PCR) by 12 months of age
13. Serious adverse events (SAEs), grade ≥3 AEs by 12 months of age

Mothers and pregnancy outcomes:
1. All-cause MA-RTI by 12 months post-delivery
2. SAEs by 12 months post-delivery
3. Pregnancy loss (miscarriage and stillbirth)
4. Preterm
5. Infant low birth weight (<2500g)

Completion date
07/03/2029

Eligibility

Key inclusion criteria
Pregnant women:
1. Pregnant woman
2. Provide informed consent before study enrolment
3. Willing and able (in the Site Investigator’s opinion) to comply with all study requirements
4. Above the national legal age of consent
5. Between 24+0 (or later as per national guidance) and 36+6 weeks of gestation
6. Able to read and complete the eHealth questionnaire in a language in which it is available
7. Willing to receive MV in pregnancy, if allocated
8. Willing for the baby to receive infant mAb, if allocated

Infant:
1. Informed consent provided by the mother and other infant's legal representative (partner/co-parent) if required by local regulations
2. Live birth to a mother enrolled in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
Female

Key exclusion criteria
Pregnant women:
1. Major illness of the maternal participant or conditions of the fetus that, in the opinion of the Site Investigator, would substantially increase the risk associated with the woman's participation in and completion of the study
2. Any suspected or confirmed condition in the fetus that, in the opinion of the Site Investigator, would contraindicate participation of the future newborn/infant in the study
3. High risk of prematurity as judged by the treating clinician
4. Multiple pregnancy (i.e. twins, triplets or more)
5. Previous participation in the PIPELINE-RSV International trial
6. Receipt of any previous RSV prevention product in this pregnancy or currently participating in another interventional RSV prevention trial
7. Any contraindication for receipt of intramuscular injection (bleeding diathesis or a condition associated with prolonged bleeding) or of vaccine (history of severe allergic reaction, e.g., anaphylaxis, to any component of the vaccine)
8. History of Guillain-Barré Syndrome

Note, all live-born infants to mothers participating in the study will be included (with consent as required), but infant mAb will not be given if contraindicated.

Date of first enrolment
05/10/2025

Date of final enrolment
05/04/2027

Locations

Countries of recruitment
United Kingdom

Belgium

Netherlands

Switzerland

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
PENTA Foundation

ROR
https://ror.org/00d7mpc92

Funder(s)

Funder type
Government

Funder Name
European Health and Digital Executive Agency

Alternative Name(s)
Health and Digital Executive Agency, HaDEA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date. Pseudonymised participant data and records will be held in the strictest confidence by the site investigator, their healthcare staff, and by all central research staff, as permitted by law.

IPD sharing plan summary
Data sharing statement to be made available at a later date