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Safety of an aerosol attenuated measles vaccine in healthy subjects with Omron's nebuliser, Aerogen's clinical nebuliser and Trudell's nebuliser

Submission date
08/05/2006

Recruitment status
No longer recruiting

Registration date
12/05/2006

Overall study status
Completed

Last Edited
10/09/2007

Condition category
Infections and Infestations

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
WHO/MAP/IN/001

Study information

Scientific Title

Study objectives
Respiratory administration of live measles vaccine closely mimics the natural route of measles infection. It is already established that current measles vaccines are more effective or equivalent in inducing antibody production when delivered by nebulisation compared to when delivered parenterally. Maternal antibody interference might be avoided or mucosal immunity might be enhanced. No increase in adverse side effects of respiratory administration has been noted compared to current injection practice. Aerosol delivery devices are available or being developed and could be used by lay people with limited training. Administration of the current measles vaccine via the respiratory route should now be comprehensively studied to achieve licensure for international use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the:
1. Research Ethics Review Committee (ERC) of the World Health Organization on the 4th April 2006
2. Health Ministry Screening Committee (HMSC) of the Ministry of Health (India) on the 17th January 2006

Study design
Multicentre, open, non-controlled, sequential by age group, parallel trial.

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Measles infection

Interventions
Attenuated measles aerosol vaccine administrated via the following devices:
1. Omron's nebuliser
2. Aerogen's clinical nebuliser
3. Trudell's nebuliser

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome(s)

Evaluation of the safety of aerosol administration of live Edmonston Zagreb attenuated measles vaccine given to healthy volunteers.

Key secondary outcome(s))
Evaluation of the serum plaque reduction neutralisation titres before and after aerosol administration of live attenuated measles vaccine given to healthy volunteers.

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Male subject, 18 to 35 years old for first group
2. Male or female at the age of 1 to 17 years for second and third group
3. Residence in the study area
4. Measles immune, as determined by Plaque Reduction Neutralisation (PRN) titre greater than 120 mIU/ml
5. Healthy on the day of the visit as supported by physical examination and laboratory evaluation on preset parameters
6. Signed informed consent (subject and/or parent/guardian/legal representative)
7. Expressed interest and availability to fulfil the study requirements
8. Non pregnant as certified by pregnancy test and agreement to avoid pregnancy for at least 30 days after vaccination (women of childbearing age)
9. Willing not to receive any experimental drug or vaccine within 90 days after study vaccination

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
1. Human Immunodeficiency Virus (HIV) positive (serology test)
2. Pregnant (based on positive pregnancy test)
3. Immunodeficiency or suppression (disease or iatrogenic induced), seizure disorder and progressive neurological disorder
4. Enrolled in any experimental drug or vaccine study within 30 days prior to vaccination
5. Known hypersensitivity to any component of the study vaccine
6. History of thrombocytopenia or immune thrombocytopenia purpura
7. Significant psychiatric or medical illness, including pulmonary disease (such as asthma requiring medication)
8. Severe malnutrition, as indicated by current guidelines by Indian Academic of Paediatrics
9. Axillary temperature greater than 38.3°C or other acute illness on the day of scheduled

vaccination
10. Household contact who has a medical history suggestive of disease or drug induced immunodeficiency or suppression (e.g. ongoing treatment with an immunosuppressive agent, chronic diarrhoea for greater than one month, fever for greater than one month, chronic cough for greater than one month, generalised dermatitis or lymphadenopathy, gastrointestinal candidiasis)
11. Receipt of any licensed vaccine within 30 days prior to vaccination

Date of first enrolment
10/05/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
India

Switzerland

Study participating centre
Initiative for Vaccine Research
Geneva-27
Switzerland
CH-1211

Sponsor information

Organisation
World Health Organization (WHO) (Switzerland)

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organization (WHO) (Switzerland)

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

IPD sharing plan summary