

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	<input type="checkbox"/> Prospectively registered
Registration date 12/05/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/09/2007	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Measles infection

Interventions

Attenuated measles aerosol vaccine administered 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 measure

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

Secondary outcome measures

Evaluation of the serum plaque reduction neutralisation titres before and after aerosol administration of live attenuated measles vaccine given to healthy volunteers.

Overall study start date

10/05/2006

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

Age group

Not Specified

Sex

Both

Target number of participants

60 subjects for 3 sequential age groups; 20 participants in each

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)

Sponsor details

Initiative for Vaccine Research
20 Avenue Appia
Geneva-27
Switzerland
CH-1211

Sponsor type

Research organisation

Website

http://www.who.int/vaccine_research/en/

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

Private sector organisation

Funding Body Subtype

International organizations

Location

Switzerland

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration