

Study of safety and immunogenicity of Measles vaccine (Rouvax®) administered by transcutaneous route (France)

Submission date 25/11/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/11/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/03/2008	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

RPC 037

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received on the 23rd March 2004.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Vaccine/immunisation

Interventions

Intervention: 1 dose of Rouvax® vaccine administered to the skin of the shoulder after stripping (abrading) the skin

Control: 1 dose of Rouvax® administered by injection

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Measles vaccine (Rouvax®)

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

23/03/2004

Completion date

23/03/2005

Eligibility

Key inclusion criteria

1. Healthy adults between 18 and 22 years of age of haplotype HLA-A201 who have previously been immunised against measles and for whom the anti-measles antibodies are low
2. Female participants must be under contraception

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

1. Previous infection with measles
2. Contra-indications to the use of Rouvax® vaccine
3. Hypersensitivity to egg proteins
4. Human Immunodeficiency Virus (HIV) seropositive
5. Treatment with corticosteroids or immunosuppressors in 15 days prior to enrolment
6. Exposure of back-skin to sun in 15 days prior to enrolment
7. Dermatological pathology on back
8. Acute and evolutive disease
9. Blood donation in three months prior to enrolment
10. In a period of exclusion following previous clinical trials
11. Having received 3800 or more Euros in preceeding 12 months from participation in clinical trials

Date of first enrolment

23/03/2004

Date of final enrolment

23/03/2005

Locations

Countries of recruitment

France

Switzerland

Study participating centre

20, Avenue Appia

Geneva-27

Switzerland

CH 1211

Sponsor information

Organisation

World Health Organization (WHO)/Department of Immunisation, Vaccines and Biologicals (IVB)
(Switzerland)

Sponsor details

20, Avenue Appia

Geneva-27

Switzerland

CH 1211

Sponsor type

University/education

Website

<http://www.who.int>

ROR

<https://ror.org/01f80g185>

Funder(s)

Funder type

Research organisation

Funder Name

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