

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

Submission date 25/11/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 25/11/2005	Overall study status Completed	☐ Protocol
Last Edited 26/03/2008	Condition category Infections and Infestations	☐ 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

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

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration