ISRCTN88861431 https://doi.org/10.1186/ISRCTN88861431

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 [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/11/2005	**Overall study status** Completed	
Last Edited 26/03/2008	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

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