ISRCTN04280032 https://doi.org/10.1186/ISRCTN04280032

Disposable-Syringe Jet Injector for Measles-Mumps-Rubella vaccine (DSJI MMR) study

Submission date	Recruitment status	[_] Prospectively registered
08/07/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/07/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2019	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Reinaldo Martins

Contact details
Av. Brasil 4365
Manguinhos
Rio de janeiro
Brazil
21040-360
+55 21 3882 9497
rmenezes@bio.fiocruz.br

Additional identifiers

Protocol serial number
Asclin/002/2009

Study information

Scientific Title
A randomised, non-inferiority study comparing safety and immunogenicity of a disposable-syringe jet injector to needle and syringe for the administration of measles-mumps-rubella combination vaccine to healthy Brazilian infants aged 12 to 18 months

Acronym
DSJI/MMR

Study objectives
Immunogenicity of measles-mumps-rubella (MMR) vaccine administered by needle free device is non inferior to that induced by needle and syringe.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved on 4th April 2010 by:
1. PATH REC (ref: 499)
2. Brazilian CONEP National Ethics Committee (ref: 15810)

Study design
Randomised controlled non-inferiority study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Measles, mumps and rubella vaccination

Interventions
MMR vaccine, against measles, mumps and rubella (Schwarz, RIT 4385 and Wistar RA 27/3 strains, respectively), to be administered as a single 0.5 mL dose, subcutaneously, delivered by a needle-free device (experimental group) or by the conventional needle and syringe method (control group), in a 2:1 proportion,
that is, 388 volunteers allocated to the experimental group and 194 to the control group. Volunteers will be followed-up for 42 days after vaccination. Blood collections for immunogenicity before vaccination and 42 days after vaccination. Adverse events will be registered in diary cards by parents/guardians during this period.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Measles-mumps-rubella vaccine

Primary outcome(s)
Antibody titres 42 days after vaccination: cut offs for enzyme-linked immunosorbent assay (ELISA) 231 units/mL (mumps) and 4 IU/mL for rubella. Plaque reduction neutralisation test (PRNT) for measles, cut off 0.20 IU/mL.

Key secondary outcome(s))
Local and systemic adverse events during 42 days after vaccination

Completion date
26/07/2011

Eligibility

Key inclusion criteria
1. Healthy children from 12 to 18 months of age, either sex
2. Up-to-date with their immunisation schedule according to age
3. Not enrolled in other clinical studies

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 months

Upper age limit
18 months

Sex
All

Total final enrolment
582

Key exclusion criteria
1. Parents/guardians unable or unwilling to give consent for the study
2. Unable to follow the study procedures

Date of first enrolment
26/07/2010

Date of final enrolment
26/07/2011

Locations

Countries of recruitment
Brazil

Study participating centre
Av. Brasil 4365
Rio de janeiro
Brazil
21040-360

Sponsor information

Organisation
Bio-Manguinhos/Fiocruz (Brazil)

ROR
https://ror.org/05gj5j117

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation (USA) - PATH DSJI project

Funder Name
Bio-Manguinhos/Fiocruz (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2015	10/07/2019	Yes	No