

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

<b>Submission date</b> 08/07/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/07/2019	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

**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**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure**

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.

**Secondary outcome measures**

Local and systemic adverse events during 42 days after vaccination

**Overall study start date**

26/07/2010

**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

**Age group**

Child

**Lower age limit**

12 Months

**Upper age limit**

18 Months

**Sex**

Both

**Target number of participants**

582 children

**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)

**Sponsor details**

Av. Brasil 4365

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**Sponsor type**

Industry

**Website**

<http://www.bio.fiocruz.br>

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

### 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2015	10/07/2019	Yes	No