

Role of oral penicillin prophylaxis in preventing serious infections in Sickle Cell Disease in children aged 3 months to 5 years: a randomised controlled trial

Submission date 18/01/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/09/2008	Condition category Haematological Disorders	<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

Dr Archana Patel

Contact details

Professor & Head
Department of Paediatrics
Indira Gandhi Government Medical College
Central Avenue Road
Nagpur
Maharashtra
India
440018
+91 (0)712 277 0509
ceuiggmc@yahoo.co.in

Additional identifiers

Protocol serial number

5/20/12/05

Study information

Scientific Title

Acronym

SCD

Study objectives

The null hypothesis is that in India, the rate of severe infection in children aged 3 months to 5 years of sickle cell anaemia receiving penicillin prophylaxis is not different from those who do not receive prophylaxis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Clinical Ethics Committee of Indira Gandhi Government Medical College, Nagpur on the 13th November 2006 (ref: I.G.G.M.C./Pharm/272/2006).

Study design

Double blind randomised controlled clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Sickle cell anaemia

Interventions

1. Oral penicillin 125 mg twice a day for children below three years and 250 mg twice a day for older children up to 5 years
2. Placebo twice a day in the same doses as above as per age groups

Most children above 2 years also received polyvalent pneumococcal vaccine.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Penicillin

Primary outcome(s)

Severe infections.

Key secondary outcome(s)

1. Mortality
2. Sickle cell crisis
3. Blood transfusion
4. Number of hospitalisation
5. Unwell days
6. Other infections

Completion date

31/10/2007

Eligibility**Key inclusion criteria**

1. Age 3 months to 5 years, either sex
2. Homozygous sickle cell (HbSS) pattern of haemoglobin (Hb) on cellulose acetate electrophoresis
3. Subjects whose parents consent to participate

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 months

Upper age limit

5 years

Sex

All

Key exclusion criteria

1. Chronic illness other than sickle cell disease (SCD)
2. On long term medication other than vitamins and trace metals
3. Any known allergy to penicillin

Date of first enrolment

01/12/2006

Date of final enrolment

31/10/2007

Locations

Countries of recruitment

India

Study participating centre

Professor & Head

Maharashtra

India

440018

Sponsor information

Organisation

Indira Gandhi Government Medical College (India)

ROR

<https://ror.org/011r34n61>

Funder(s)

Funder type

University/education

Funder Name

Indira Gandhi Government Medical College, Nagpur (India) - institutional funding (ref: 5/20/12/05)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration