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# 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

**Registration date**
12/09/2008

**Overall study status**
Completed

**Last Edited**
12/09/2008

**Condition category**
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] 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

**EudraCT/CTIS number**

**IRAS number**

### ClinicalTrials.gov number

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### 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 measure
Severe infections.

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

### Overall study start date
01/12/2006

### 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

### Age group
Child

### Lower age limit
3 Months

### Upper age limit
5 Years

### Sex
Both

### Target number of participants
65

### 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)

### Sponsor details
Dean
Central Avenue Road
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Maharashtra
India
440018

### Sponsor type
University/education

### Website
http://www.igmcshimla.org/

### 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

**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