

# 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

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

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### Contact details

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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. Sick 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

Nagpur

Maharashtra

India

440018

**Sponsor type**

University/education

**Website**

<http://www.igmcshimla.org/>

ROR

## **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