

# 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

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