

# Oral rifampin-cotrimoxazole combination versus intravenous cloxacillin in chronic staphylococcal osteomyelitis: a long-term follow-up trial

<b>Submission date</b> 21/12/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/02/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/02/2008	<b>Condition category</b> Musculoskeletal Diseases	<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

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## Additional identifiers

## Study information

**Scientific Title**

**Study objectives**

Oral rifampin-cotrimoxazole combination may be as useful as the standard intravenous cloxacillin therapy against chronic osteomyelitis by *Staphylococcus aureus*.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from the Investigation Committee of Hospital de Bellvitge in January 1991.

### **Study design**

Single centre interventional randomised, active controlled study

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Non-axial chronic osteomyelitis due to *Staphylococcus aureus*

### **Interventions**

After surgery and identification of *Staphylococcus aureus* upon surgical samples, randomisation of patients for antibiotic therapy:

Group A: intravenous cloxacillin (2 g every four hours [q4h]) for 6 weeks followed by oral cloxacillin (500 mg every six hours [q6h]) for 2 weeks

Group B: oral rifampin-cotrimoxazole combination for 8 weeks (rifampin 600 mg every 24 hours [q24h] plus 7 - 8 mg/kg per day of trimethoprim component, equivalent to three simple strength cotrimoxazole capsules, every 12 hours [q12h])

The total duration of the protocol treatment was 8 weeks for both groups (6 intravenous [iv] and 2 oral [po] in the cloxacillin group and 8 po in the rifampin-cotrimoxazole group). The duration of the follow-up is from the end of antibiotic therapy until 2007 (a median of 10 years).

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Cloxacillin, rifampin-cotrimoxazole, trimethoprim

### **Primary outcome(s)**

Treatment failure rate, defined as the number of cases with clinical relapse (appearance or recurrence of local inflammatory signs or sinus tract drainage, with or without microbiological confirmation) during follow-up.

### **Key secondary outcome(s)**

1. Treatment tolerability and compliance (number of patients who did not fulfil protocol treatment and reason), from patient inclusion to the end of antibiotic therapy (8 weeks)
2. Length of hospital stay (days) for each treatment schedule; defined as hospitalisation during the diagnosis and treatment of the episode

**Completion date**

31/12/1996

## Eligibility

**Key inclusion criteria**

Adult patients (greater than 18 years old) of any gender with chronic osteomyelitis by *Staphylococcus aureus* treated with surgery.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Prosthetic joint infection
2. Methicillin resistant *Staphylococcus aureus*
3. Allergy to protocol antibiotics
4. Strain resistance to cotrimoxazole or rifampin

**Date of first enrolment**

01/04/1991

**Date of final enrolment**

31/12/1996

## Locations

**Countries of recruitment**

Spain

**Study participating centre**

## **Hospital de Bellvitge**

Barcelona

Spain

08907

## **Sponsor information**

### **Organisation**

Institute of Biomedical Investigations of Bellvitge (Institut d'Investigació Biomèdica de Bellvitge) (IDIBELL) (Spain)

### **ROR**

<https://ror.org/0008xqs48>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Hospital de Bellvitge (Spain)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

### **IPD sharing plan summary**

Not provided at time of registration