

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

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

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

N/A

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/04/1991

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Exploratory study. Fifty patients included

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)

Sponsor details

c/o Dr. Javier Ariza Cardenal

Hospital de Bellvitge

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08907

Sponsor type

Hospital/treatment centre

Website

<http://www.idibell.es>

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital de Bellvitge (Spain)

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