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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

Registration date
05/02/2008

Overall study status
Completed

Last Edited
05/02/2008

Condition category
Musculoskeletal Diseases

[ ] 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

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-cotrimoxazol 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
Feixa Llarga s/n
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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