APPENDIX 3

Administrative information

Title

A multicentre, randomised, phase III, open study to assess the efficacy of daptomycin plus fosfomycin versus daptomycin monotherapy for treatment of methicillin-resistant *Staphylococcus aureus* bacteraemia in hospitalised patients

Trial registration

Sponsor protocol code: BACSARM

EudraCT number: 2013-000586-37

Clinical trial registration: NCT01898338

Protocol version

version 4. 30th April 2014

Funding

The trial is supported by grant funding from the National Institute of Health Research, Instituto de Salud Carlos III (ISCIII), Ministerio de Economía y Competitividad. Gobierno de España (Expediente PI12/01907)

Roles and responsibilities

Miquel Pujol. Department of Infectious Diseases. Hospital Universitari de Bellvitge-IDIBELL: study sponsor; study design; recruitment of patients.

Evelyn Shaw. Department of Infectious Diseases. Hospital Universitari de Bellvitge-IDIBELL: study design; review of the protocol; recruitment of patients.

JM Miró. Department of Infectious Diseases. Hospital Universitari Clínic de Barcelona-IDIBAPS: Study design, review of the protocol.

J Carratalà. Department of Infectious Diseases. Hospital Universitari de Bellvitge-IDIBELL: Study sponsor; study design; recruitment of patients

C de la Calle. Department of Infectious Diseases. Hospital Universitari Clínic de Barcelona-IDIBAPS: review of the protocol; recruitment of patients

M Puig-Asensio and C Pigrau. Department of Infectious Diseases. Hospital Universitari Vall d'Hebron, Barcelona: review of the protocol; recruitment of patients

J López-Contreras. Department of Infectious Diseases. Hospital Universitari Santa Creu y Sant Pau, Barcelona: review of the protocol; recruitment of patients

M Montero. Department of Infectious Diseases. Hospital Universitari Parc de Salut Mar, Barcelona: review of the protocol; recruitment of patients

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G García-Pardo. Department of Internal Medicine. Hospital Universitari Joan XXIII, Tarragona: review of the protocol; recruitment of patients

F Barcenilla. Unit of Hospital Infection Control. Hospital Universitari Arnau de Vilanova, Lleida: review of the protocol; recruitment of patients

E Calbo. Department of Internal Medicine. Hospital Universitari Mutúa de Terrassa, Barcelona: review of the protocol; recruitment of patients

E Espejo. Department of Internal Medicine. Hospital de Terrassa, Terrassa, Barcelona: review of the protocol; recruitment of patients

O Gasch. Department of Infectious Diseases. Corporació Sanitaria Parc Taulí, Sabadell, Barcelona: review of the protocol; recruitment of patients

B Padilla. Department of Microbiology and Infectious Diseases. Hospital Universitario Gregorio Marañón, Madrid: review of the protocol; recruitment of patients

A García-Reyne. Department of Internal Medicina. Hospital Universitario 12 de Octubre, Madrid: review of the protocol; recruitment of patients

V Pintado. Department of Infectious Diseases. Hospital Universitario Ramón y Cajal, Madrid: review of the protocol; recruitment of patients

J Rodriguez-Baño. Department of Infectious Diseases. Hospital Universitario Virgen Macarena, Sevilla: review of the protocol; recruitment of patients

J Paquau. Department of Infectious Diseases. Hospital Universitario Virgen de las Nieves, Granada: review of the protocol; recruitment of patients

M Montejo. Unit of Infectious Diseases. Hospital Universitario de Cruces, Barakaldo: review of the protocol; recruitment of patients

M Salavert. Department of Infectious Diseases. Hospital Universitario I Politècnic la Fe, Valencia: review of the protocol; recruitment of patients

J Murillas. Department of Internal Medicine. Hospital Universitario Son Espases, Mallorca: review of the protocol; recruitment of patients

M J García-País. Department of Internal Medicine. Hospital Universitario Lucus Augusti, Lugo: review of the protocol; recruitment of patients

Name and contact information of the trial sponsor

Miquel Pujol

Department of Infectious Diseases

Hospital Universitari de Bellvitge-IDIBELL

Feixa Llarga s/n

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08907 L'Hospitalet de Llobregat
Barcelona, Spain
Tel. +34 93 260 73 83
Fax. + 34 93 260 72 74
Email: mpujol@bellvitgehospital.cat

Role of study sponsor and funders

The sponsor made the study design. He will take part in interpretation of data and also commits to publishing this data within twelve months of the completion of the study. Results will be analysed and reported in accordance with CONSORT guidelines. He will have ultimate authority over writing of the report and the decision to submit the report for publication.

Funders have no role in the study.

Monitoring committe

An independent monitoring committee will ensure the correct progress of the research and the efficacy of the data towards achieving the goals of the study. This committe depends on Clinical Research Unit (UCICEC)-IDIBELL, in Hospitalet de Llobregat, Barcelona . http://www.idibell.cat/modul/ucicec/en