ISRCTN74215569 https://doi.org/10.1186/ISRCTN74215569

A phase 3 study to determine the efficacy and safety of recombinant human activated protein C in severe sepsis

Submission date	Recruitment status	[_] Prospectively registered
06/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/08/2008	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr William Macias

Contact details
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Eli Lilly and Company
307 E. McCarty St.
Indianapolis
United States of America
46285

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
F1K-MC-EVAD

Study information

Scientific Title

Acronym
PROWESS

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

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
Severe sepsis

Interventions
Recombinant human activated protein C (tradename - Xigris, generic name - drotrecogin alfa [activated]) versus placebo.

This trial took place at 164 hospitals in 11 countries.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)

Recombinant human activated protein C

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/1998

Completion date
01/06/2000

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
1,690

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/07/1998

Date of final enrolment
01/06/2000

Locations

Countries of recruitment
Belgium

Canada

France

Spain

United States of America

Study participating centre
DC6072
Indianapolis
United States of America
46285

Sponsor information

Organisation
Eli Lilly and Company (USA)

Sponsor details
DC6072
307 E. McCarty Street
Indianapolis
United States of America
46285

Sponsor type
Industry

ROR
https://ror.org/00cpsd622

Funder(s)

Funder type
Industry

Funder Name
Eli Lilly and Company (USA)

Alternative Name(s)
Lilly, Eli Lilly & Company, Eli Lilly & Co., Eli Lilly And Co

Funding Body Type
Government organisation

Funding Body Subtype

For-profit companies (industry)

Location
United States of America

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/03/2001		Yes	No
Results article	results	01/04/2004		Yes	No