

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

Submission date

06/01/2004

Recruitment status

No longer recruiting

Registration date

07/01/2004

Overall study status

Completed

Last Edited

08/08/2008

Condition category

Infections and Infestations

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr William Macias

Contact details

DC6072

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 (trade name - 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