ISRCTN95777824 https://doi.org/10.1186/ISRCTN95777824

Regenerative effects of erythropoietin in burn and scald injuries

Submission date	Recruitment status	[X] Prospectively registered
19/01/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/04/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/02/2021	Injury, Occupational Diseases, Poisoning	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Hans-Günther Machens

Contact details
Clinic for Plastic Surgery and Hand Surgery
University Hospital Rechts der Isar
Technische Universitaet Munchen
Ismaninger Str, 22
Munchen
Germany
81675

Additional identifiers

Clinical Trials Information System (CTIS)
2006-002886-38

Protocol serial number
UKSH-0506; 0506

Study information

Scientific Title

A multicentre study on regenerative effects of low-dose erythropoetin in burn and scald injuries

Acronym
EPO in burns

Study objectives
Current hypothesis as of 22/01/2009:
The study aim is to prove a cytoprotective and regenerative effect Erythropoietin in thermally injured patients in terms of reduced morbidity and mortality.

Initial information at time of registration:
The study aim is to prove a cyto-protective and regenerative effect of low-dose erythropoietin (LDE) in thermally injured patients in terms of reduced morbidity and mortality.

Please note that as of 22/01/2009 this record has been extensively amended. All updates can be found in the relevant section under the above update date. At this time, the anticipated start and end dates have also been amended. The initial trial dates were as follows:
Initial overall trial start date: 01/05/2007
Initial overall trial end date: 01/05/2010

Please also note that as of 22/01/2009 the sponsor has also changed. The initial sponsor at time of registration was:
University Medical Centre Schleswig-Holstein (Germany)
Campus Lübeck
Ratzeburger Allee 160
Lübeck
23538
Germany

Please note that as of 30/04/2013, the overall trial end date was changed from 01/02/2013 to 30 /09/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Medical Centre Schleswig-Holstein, 21/12/2006, ref: 06-177. An amendment was approved on 22/09/2008.

Study design
Randomised-controlled double-blind trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Thermal injuries

Interventions
Current interventions as of 22/01/2009:
Erythropoietin 150 IU/kg body weight/application every second day. Subcutaneous drug administration every other day will be performed over 3 weeks.

Initial information at time of registration:
Erythropoietin 200 IE/kg body weight per week. Subcutaneous drug administration every other day will be performed over 4 weeks after injury.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Erythropoietin

Primary outcome(s)
Current outcomes as of 22/01/2009:
Time until complete re-epithelialisation of SGDS at a definite location on the lateral upper thigh.

Initial information at time of registration:
Time until complete re-epidermalisation of split skin donor sites at the right medial upper thigh.

Key secondary outcome(s))
Current outcomes as of 22/01/2009:
1. Time until complete wound healing of type 2a SDW
2. Time until complete wound healing of skin graft
3. Cellular and molecular regenerative effects in SGDS and type 2a SDW, endothelial progenitor cell (EPC) recruitment, EPO receptor upregulation, protein expression
4. Quality of scar formation in conservatively and operatively treated wound locations
5. Number of packed red cells units, which are transfused during the treatment interval
6. Laboratory parameters (differential blood cell count, iron storage, EPO)
7. Cardiopulmonary parameters
8. Quality of life 12 months after trauma
9. Mortality (within 21 days, hospital stay and 1 year)
10. Adverse events
11. Gender differences in monitored data

Initial information at time of registration:
1. Number of packed red cells units, which are transfused during the treatment interval
2. Laboratory parameters (differential blood cell count, iron storage, erythropoietin [EPO])
3. Cardiopulmonary and renal parameters
4. Time until complete wound healing of deep 2° thermal wounds is achieved
5. Scar formation in conservatively and operatively treated wound locations
6. Quality of life 12 months after hospital discharge
7. Mortality (within 28 days, hospital stay and 1 year)
8. Adverse effects

Completion date

30/09/2013

Eligibility

Key inclusion criteria
Current criteria as of 22/01/2009:
1. 2° and 3° burn and scald thermal injuries, which require operations including split skin harvesting and grafting
2. Men and women, aged greater than 18 and less than or equal to 75 years
3. Secure contraception

Initial information at time of registration:
1. Deep 2° and 3° burn and scald thermal injuries, which require operations including split skin harvesting and grafting
2. Aged greater than or equal to 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
116

Key exclusion criteria
Current exclusion criteria as of 30/04/2013:
1. Admission later than 24 hours after injury
2. Haematological disorders (anaemia, lymphoma, leukaemia, inborn coagulation diseases)
3. Pregnancy or breast-feeding
4. Estimated survival shorter than one week (Abbreviated Burn Severity Index [ABSI] greater than 12) in patient older than 40 years of age
5. Total burn surface area involved less than 60% in patients older than 40 years of age, in patients younger than 40 years of age no limitation of maximum burned body surface and no limitation of ABSI score will be considered
6. Body weight less than 50 kg or greater than 110 kg
7. Upper lateral thights of leg thermally injured
8. Subject is the investigator or any sub-investigator, research assistant, pharmacist, study coordinator, other staff or relative there of directly involved in the conduct of the protocol
9. Subject unlikely to comply with protocol, e.g., uncooperative attitude, inability to return for follow-up visits, and unlikelihood of completing the study

10. Treatment with any investigational product in the last 12 months before study entry
11. Treatment with any immunosuppressive therapy, cancer-related chemotherapy or radiation therapy in the past 12 months
12. History of hypersensitivity to the investigational products
13. Likelihood of requiring treatment during the study period with drugs not permitted by the clinical study protocol
14. Clinically relevant cardiovascular (s.p. cardiac infarction, coronary heart disease [CHD], thromboembolic disease, thromboembolic events shortly before admission), hepatic (Child B or C liver disease), endocrine (morbid obesity: body mass index [BMI] greater than 40) or systemic (cancer) disease (malignoma)
15. Epileptiform diseases
16. Phenylketonuria
17. Human immunodeficiency virus (HIV) disease, acquired immune-deficiency virus (AIDS)
18. Informed consent missing

Previous exclusion criteria as of 22/01/2009:
Subjects presenting with any of the following will not be included in the study:
1. Admission later than 24 hours after injury
2. Informed consent given later than 48 hours after trauma
3. Suicide attempt
4. Skin Graft Donor Site (SGDS) created later than 4 days after trauma
5. Begin of treatment with study drug less than 24 hours before creation of SGDS
6. Haematological disorders (anaemia, lymphoma, leukaemia, inborn coagulation diseases)
7. Pregnancy or breast-feeding
8. Estimated survival shorter than one week (Abbreviated Burn Severity Index [ABSI] greater than 12)
9. Total burn surface area involved less than 10% or greater than 50%
10. Body weight less than 50 kg or greater than 110 kg
11. Upper lateral thigh of leg thermally injured
12. Subject is the investigator or any sub-investigator, research assistant, pharmacist, study coordinator, other staff or relative thereof directly involved in the conduct of the protocol
13. Subject unlikely to comply with protocol, e.g., uncooperative attitude, inability to return for follow-up visits, and unlikelihood of completing the study
14. Treatment with any investigational product in the last 12 months before study entry
15. Treatment with any immunosuppressive therapy, cancer-related chemotherapy or radiation therapy in the past 12 months
16. History of hypersensitivity to the investigational products
17. Likelihood of requiring treatment during the study period with drugs not permitted by the clinical study protocol
18. Clinically relevant cardiovascular (s.p. cardiac infarction, coronary heart disease [CHD], thromboembolic disease, thromboembolic events shortly before admission), hepatic (Child B or C liver disease), endocrine (morbid obesity: body mass index [BMI] greater than 40 kg/m^2) or systemic (cancer) disease (malignoma)
19. Epileptiform diseases
20. Phenylketonuria
21. Human immunodeficiency virus (HIV) disease, acquired immune-deficiency virus (AIDS)
22. Informed consent missing

Initial information at time of registration:
1. Haematological disorders (e.g. leukaemia, inborn coagulation diseases)
2. Pregnancy or breast-feeding
3. Estimated survival shorter than one week (Abbreviated Burn Severity Index [ABSI] > 12)

4. Total burn surface area involved > 40 %
5. Upper lateral thigh of both legs thermally injured
6. Subject is the investigator or any subinvestigator, research assistant, pharmacist, study coordinator, other staff or relative thereof directly involved in the conduct of the protocol
7. Subject unlikely to comply with protocol, e.g. uncooperative attitude, inability to return for follow-up visits, and unlikelihood of completing the study
8. Treatment with any investigational product in the last 12 months before study entry
9. Treatment with any anti-cancer chemotherapy in the past 12 months
10. History of hypersensitivity to investigational products or drugs with similar chemical structures
11. Likelihood of requiring treatment during the study period with drugs not permitted by the clinical study protocol
12. Clinically relevant cardiovascular, hepatic, neurologic, endocrine, or other major systemic disease making implementation of the protocol or interpretation of the study results difficult (e. g. Marfans syndrome, Child B or C liver disease, Morbid obesity [Body Mass Index > 40])
13. Informed consent missing

Date of first enrolment
01/08/2008

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
Germany

Study participating centre
Clinic for Plastic Surgery and Hand Surgery
Munchen
Germany
81675

Sponsor information

Organisation
Munich Technical University (Technische Universitaet Munchen) (Germany)

ROR
https://ror.org/02kkvpp62

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany)

Results and Publications

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	31/10/2018	18/02/2021	Yes	No
Protocol article	protocol	03/05/2013		Yes	No