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Clinical trial on enzymatic agent Salizolis

Submission date	Recruitment status	[ ] Prospectively registered
09/11/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/12/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/03/2008	Injury, Occupational Diseases, Poisoning	[ ] 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

Acronym
SALIZOLIS

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Wounds

Interventions
The randomised and controlled, single blind and parallel group study will be carried out on two groups. Each group consists of 15 patients.
Patients of group A are being treated according to the current standards of therapy. The wounds will be self-purged out of necrotic tissues.
Patients of group B are being treated according to the new regimen under investigation - enzymatic agent Salizolis. Necrotic tissue of the wounds will be purged out by enzymatic agent.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2004

Completion date
31/12/2005

Eligibility

Key inclusion criteria
Patients with acute and chronic wounds containing necrotic tissue (thermal and chemical burns, frostbites, trophic ulcers, injuries of truncal and limb, injuries of wrist and hand, injuries of tarsus and foot, varicosis of lower limbs with ulcers and inflammation, foot ulcers, pressure sores, infections on dermal and hypodermal tissue and other purulent inflammations).

Inclusion criteria:
1. Older than 18 years

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
30

Key exclusion criteria
1. Children under the age of 18
2. Pregnant women
3. Soldiers of active service
4. Incurable patients
5. Patients with mental disorder
6. Patients dependent on drugs and alcohol
7. Subjects incapable of giving consent
8. Subjects disagree with participation in clinical trial

Date of first enrolment
01/12/2004

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Lithuania

Study participating centre
Kaunas Medical University Hospital
Kaunas
Lithuania
50009

Sponsor information

Organisation
JSC Biocentras (Lithuania)

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Sponsor type
Industry

Website
http://www.biocentras.lt/about_en.html

ROR
https://ror.org/005gk6w44

Funder(s)

Funder type
Government

Funder Name
Sixth framework programme horizontal research activities involving small and medium sized enterprises (SMEs) co-operative research project - Ultimate Pressure Dressing System for the Management of Venous Ulcers (European Union)

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