

Clinical trial on enzymatic agent Salizolis

Submission date 09/11/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/12/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/03/2008	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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)

Sponsor details

Graiciuno str. 10

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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