# 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

#### Contact name

Dr Rimdeika Rytis

#### Contact details

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## Additional identifiers

**Protocol serial number** 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

#### Study type(s)

Treatment

#### 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(s)

Not provided at time of registration

#### Key secondary outcome(s))

Not provided at time of registration

#### 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

#### Healthy volunteers allowed

No

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

#### 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)

#### **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**

Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration