

# Thrombolysis With Recombinant Non-immunogenic Staphylokinase vs Surgery in Patients With Acute Limb Ischemia FORAT Trial

NCT05372718

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Status	RECRUITING
Phase	Phase 3
Sponsor	Supergene, LLC
Enrollment	170 participants

## Key Eligibility Criteria

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### Inclusion (6)

- Men and women aged 18 and older;
  - Diagnosis of I-II b degree of ALI;
  - Patient consent to use reliable contraceptive methods throughout the study and for 3 weeks after:
  - women who have a negative pregnancy test and use the following contraceptives: intrauterine devices, oral contraceptives, contraceptive patch, prolonged injectable contraceptives, double barrier method of contraception. Women who are not fertile can also take part in the study (documented conditions: hysterectomy, tubal ligation, infertility, menopause for more than 1 year);
  - men using barrier contraception. The study may also involve men who are not fertile (documented conditions: vasectomy, infertility);
- ... and 1 more (see full listing online)

### Exclusion (8)

- Extensive bleeding at present;
  - Intracranial (including subarachnoid) hemorrhage at present;
  - Recent gastrointestinal bleeding (within 10 days);
  - Major surgery or major trauma within the previous 3 months, recent traumatic brain injury;
  - Systolic blood pressure above 180 mm Hg or diastolic blood pressure above 110 mm Hg or the need for intravenous drugs to lower blood pressure to these limits;
- ... and 3 more (see full listing online)

## Locations (8 total)

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Kursk city emergency hospital, Kursk, Kursk Region, Russia  
Sergiyev Posad Regional Clinical Hospital, Sergiyev Posad, Moscow Oblast, Russia  
Kaliningrad Regional Clinical Hospital, Kaliningrad, Russia  
... and 5 more locations