

The Endovascular Plus GENE Therapy Versus Only EndoVascular Therapy for Severe Limb ischaemia Trial

NCT06473740

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| Status | RECRUITING |
| Phase | Phase 4 |
| Sponsor | Amur State Medical Academy |
| Enrollment | 386 participants |

Key Eligibility Criteria

Inclusion (22)

- Men and women 18 years of age and older;
 - Atherosclerotic infrainguinal disease of the peripheral arteries (occlusive-stenotic lesion below the inguinal fold);
 - Severe ischemia of the lower extremity, characterized by pain at rest or a non-healing ischemic ulcer, which corresponds to Rutherford categories 4-5 and Fontaine grades III-IV;
 - Without any previous surgical intervention of the ipsilateral n/a below the inguinal fold;
 - Suitable for endovascular treatment according to researchers;
- ... and 17 more (see full listing online)

Exclusion (7)

- Refusal of the patient to further participate in the study;
 - Use of drugs from the list of prohibited concomitant therapy;
 - The use of any other concomitant therapy that, in the opinion of the investigator, may interfere with the assessment of the effectiveness and safety of the investigational medicinal product and/or distort the results of the study;
 - Onset of pregnancy;
 - Injuries and damage to the ipsilateral lower limb, which, in the opinion of the investigator, may interfere with the assessment of the effectiveness and safety of the study drug and/or distort the results of the study;
- ... and 2 more (see full listing online)

Locations (1 total)

Amur State Medical Academy, Blagoveshchensk, Amur Oblast, Russia