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Does performing amputation of lower limb due to gangrene in critically ill patients in two stages allow improved results of treatment compared to single-stage amputation?

Submission date
06/07/2020

Recruitment status
No longer recruiting

Registration date
07/07/2020

Overall study status
Completed

Last Edited
16/03/2021

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The death of tissue as a result of deficient blood supply (ischaemic gangrene) is treated by amputation of the affected body part. This results in a large number of wound complications and death. There are two methods of amputation in common use, one-stage and two-stage. Two-stage amputation is a well-known way to reduce wound complications in patients with a high risk of infection (e.g. contaminated trauma or infected diabetic foot), but there is still lack of evidence if it can lower the mortality in severely ill patients with a complicated background of diseases.

Who can participate?
Patients requiring urgent amputation.

What does the study involve?
Records were collected for patients who had either had amputation using intensive treatment during 24 - 72 hours before surgery, and then fulfil one-stage amputation, or immediate guillotine amputation followed by reampuation after stabilisation.

What are the possible benefits and risks of participating?
None (retrospective study)

Where is the study run from?
Vinogradov Moscow Municipal hospital (Russia)

When is the study starting and how long is it expected to run for?
December 2017 to December 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Vitaly Tsvetkov, tsvetkow@yandex.ru

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Two-phase versus one-stage amputation of lower limbs among critically ill patients with ischemic gangrene as a way to reduce lethality and improve treatment outcome. Retrospective cohort trial.

Acronym
TPACIP

Study objectives
Use of urgent guillotine amputation of lower limb in critically ill patients with ischaemic gangrene as the first stage of surgical treatment allows to reduce lethality, number of wound complications and improve functional result.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/02/2018, Local Ethics Committee of the V.V. Vinogradov Moscow Municipal Hospital (61, Vavilova str., Moscow, Russia; no telephone number provided; ezhovalg@mail.ru), ref: none provided

Study design
Observational cohort retrospective study in two clinical centers

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
n/a (retrospective review of patient records)

Health condition(s) or problem(s) studied
Ischaemic gangrene of lower limb

Interventions
Retrospective comparison of two approaches to the treatment of critically ill patients who admit to the hospital due to ischaemic gangrene of lower limb.
In 2011- 2014 (control group) the tactic was to perform intensive treatment during 24 - 72 hours before surgery, and then fulfil one-stage amputation with primary formation of the stump.
In 2014 - 2018 (main group) the patients underwent urgent guillotine amputation or knee disarticulation, and then, after normalisation or stabilisation of general condition, reamputation with formation of the stump was performed.
The goal of the study is to compare these surgical tactics and their influence at the lethality, number of wound complications and functional

Records are gathered for patients in two groups:
1. Two-phase amputation including urgent guillotine amputation or knee disarticulation as a first stage an then reamputation with shaping of stump after stabilisation of patient general condition.
2. Intensive treatment before surgery, then one-stage amputation.

Intervention Type
Procedure/Surgery

Primary outcome measure

Lethality of procedure measured using patient records at a single time point

Secondary outcome measures
Measured using patient records at a single time point:
1. Number of wound complications
2. Levels of amputation

Overall study start date
20/12/2017

Completion date
29/12/2018

Eligibility

Key inclusion criteria
1. Need to perform urgent (within 72 hours after admission to the hospital) high amputation of the lower extremities in patients with critical limb ischemia who were admitted in a severe or extremely severe condition. The indication for amputation was gangrene accompanied by a progressive infection of soft tissues or a syndrome of endogenous intoxication caused by ischemic damage to the muscle tissue of the limb.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300

Total final enrolment
393

Key exclusion criteria
1. Patients with surgical soft tissue infection but without occlusion of the main arteries (including patients with extensive limb phlegmons with a neuropathic form of diabetic foot syndrome)
2. Patients with planned indications for amputation (including those operated within 72 hours after admission), e.g., patients with critical ischemia and gangrene of the limb if angiosurgical intervention is impossible or unsuccessful
3. Patients in whom the indications for urgent amputation of the limbs occurred during their stay in the hospital

Date of first enrolment
01/01/2011

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Russian Federation

Study participating centre
Vinogradov Moscow Municipal hospital
61, Vavilova str.
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Study participating centre
Moscow Municipal Clinical hospital 53
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Sponsor information

Organisation
Sechenov University

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Sponsor type
University/education

Website
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ROR
https://ror.org/02yqqv993

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Publication in peer-reviewed journal.

Intention to publish date
01/09/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request after the results have been published.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/11/2020	16/03/2021	Yes	No