Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the effect of modified tourniquet in the success of peripheral venous catheter Placement in patients admitted to Hospital

Protocol summary

Study aim

Determination of the effect of modified tourniquet in success rate of peripheral venous catheter placement in hospitalized patients.

Design

This study will be performed in the form of a clinical trial, with parallel groups, without blinding and with random allocation of patients in the intervention and control groups. A total of 142 patients, including 71 patients in the intervention group (access to a vein using a modified tourniquet) and 71 patients in the control group (access to a vein using a normal tourniquet) will participate in the study.The random allocation rule without substitution will be used for randomization and sealed envelopes will be used for concealment.

Settings and conduct

This study will be performed as a clinical trial in the emergency department of Shahid Beheshti Hospital in Bandar Anzali. Initially, a demographic and clinical information form will be completed for the candidates. After randomly assigning the samples to the intervention and control groups and completing the demographic information by the researcher through the file and interviewing them, the process of access to the peripheral vein will begin.

Participants/Inclusion and exclusion criteria

Inclusion criteria: no life-threatening condition, need to establish an intravenous route, consent to participate in the study, age between 18 to 65 years, no pregnancy, alertness.Exclusion criteria: Having skin or vascular disorders, bleeding disorders and pain.

Intervention groups

In the intervention group, a modified torque will be used to access patients' veins. In the control group, a normal tourniquet will be used to check access to patients' veins.

Main outcome variables

Success in venous catheter placement and the time taken to successfully insert the venous catheter using a conventional tourniquet and a modified tourniquet.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080818001048N5**
Registration date: **2021-05-20, 1400/02/30**
Registration timing: **prospective**

Last update: **2021-05-20, 1400/02/30**
Update count: **0**

Registration date

2021-05-20, 1400/02/30

Registrant information

Name
Rasol Tabari
Name of organization / entity
Gilan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 13 1322 1572
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rtabari@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of modified tourniquet in the success of peripheral venous catheter Placement in patients admitted to Hospital

Public title
Evaluation of the effect of modified tourniquet in the success of peripheral venous catheter Placement

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
No life threatening condition Need to establish an intravenous route Having the consent to participate in the study Age between 18 to 65 years No pregnancy alertness

Exclusion criteria:
Having skin or vascular disorders Having bleeding disorders Suffering acute pain in any organ of the body during sampling

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **142**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients will be assigned to each of the two study groups using the law of non-replacement random allocation. For this purpose, researchers will first prepare the cards by considering the total sample size to the total number of people, in which half of the cards contain the word intervention group and in the other half the word control group. These cards are placed in a lottery container without any writing on them, and then a card is randomly recorded for each patient without being removed from the container and a sequence is created. This will be repeated until the end of sampling. Accordingly, according to the sample size, 142 cards will be prepared, in which half of the cards will have the word intervention group and in the other half the word control group (71 cards in each group), then the cards will be placed in sealed envelopes and in the container. Draw. Then, for each patient, a card is removed from the container without replacement and the created sequence is recorded. This will be repeated until the end of sampling. The hiding method will be done through sealed envelopes.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Commitee of Guilan University Of Medical Science

Street address
Deputy of Research and Technology of Guilan University of Medical Sciences., In front of 17Sharivar Hospital., Shahid Siadati St., Namjoo Blvd.

City
Rasht

Province
Guilan

Postal code
4146939114

Approval date
2021-04-21, 1400/02/01

Ethics committee reference number
IR.GUMS.REC.1400.026

Health conditions studied

1

Description of health condition studied
people recourse to medical centers for examination or treatment of the disease.

ICD-10 code
Z00

ICD-10 code description
Encounter for general examination without complaint, suspected or reported diagnosis

Primary outcomes

1

Description
The success of peripheral venous catheter Placement

Timepoint
Maximum One minute after the start of the intervention

Method of measurement
Stopwatch, View the vein

Secondary outcomes

1

Description
The time taken to successfully access the peripheral vein

Timepoint
Maximum One minute after the start of the intervention
Method of measurement
Stopwatch

Intervention groups

1

Description
Intervention group: In the intervention group, a modified tourniquet will be used to access patients' veins. This tool is similar to a sphygmomanometer with a width of 5 cm and a length of 50 cm.The subjects will be lying on their backs and in complete relaxation. Access to the peripheral vein of the antecubital region will be in the right hand. Patients' blood pressure will be measured and recorded before the procedure. The modified instrument is closed around the patient's arm (5-10 cm above the antecubital area), the cuff pressure will be adjusted so that it is higher than the patient's diastolic pressure and less than the systolic pressure (mean systolic and diastolic pressure of the patient). The nursing specialist will hold the patient's hand in that position for a maximum of one minute, in which the protrusion and palpability will also record the vein being visible. After selecting the location, the appropriate catheter (preferably catheter 20) into the site. The access result is also recorded on the first attempt and the time spent for successful access to the vein. Catheter placement in both groups of patients is performed by a trained and trained nurse in finding vein and has 5 years of clinical experience with a suitable catheter by sterile method.
Category
Treatment - Devices

2

Description
Control group: In the control group, a normal tourniquet will be used to check access to the vein. The subjects will be lying on their backs in complete relaxation. The preferred place of access will be the peripheral vein of the antecubital area of the right hand. And the patient will be asked to punch his hand. The nursing specialist will hold the patient's hand in that position for a maximum of one minute, in which the protrusion and palpability will also record the vein being visible. After selecting the location, the appropriate catheter (preferably catheter 20) into the site. The access result is also recorded on the first attempt and the time spent for successful access to the vein. Catheter placement in both groups of patients is performed by a trained and trained nurse in finding vein and has 5 years of clinical experience with a suitable catheter by sterile method.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital Bandar-e Anzali
Full name of responsible person
Dr. Rasoul Tabari
Street address
km 5 Astara Road, Bandar-e Anzali, Guilan
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Bandar-e Anzali
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Guilan
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4319893151
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Rasoul Tabari Khomeiran
Street address
Faculty of Nursing and Midwifery., Daneshjo St., shahid Beheshti highway.
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Rasoul Tabari Khomeiran

Position
Assistant Professor of Guilan University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
Associate Professor of Guilan University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Full name of responsible person
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Position
Assistant Professor of Guilan University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All the data of this research can be share after coding the identity information of individuals and non-identifiable the participants in the study in the form of an Excel file entitled "Research Data Sheet Code" along with the guide codes of the variables.

When the data will become available and for how long
The begins of the data access period of this research will be immediately after the publication of the results in a scientific journal.

To whom data/document is available
All qualified university researchers will be allow to access the data of this research by submitting a request.

Under which criteria data/document could be used

The use of the data of this research for the purpose of secondary analysis of the data will be allowed by observing the principles of intellectual property and the explicit and clear request of the applicant regarding the use of the data.

From where data/document is obtainable

Dr. Rasoul Tabari (moderator of project) / Address: Faculty of Nursing and Midwifery, Daneshjo St, shahid Beheshti highway, Rasht, Guilan. Postal code: 41469-39841 Email: rtabari@gums.ac.ir Tandis sayyad ghobadi / Address: Shahid Beheshti Hospital Bandar-e Anzali, km 5 Astara Road, Bandar-e Anzali, Guilan. Postal code: 43198-93151 Email: www.tandisghobadi@gmail.com

What processes are involved for a request to access data/document

The applicant for the data must first send a request in which have a clearly stated application (how to use the data and a commitment to adhere to the ethical principles and intellectual property of using the data in accordance with ICMJE guidelines) with any identification or introduction that indicates his/her scientific competence to access the data to the executor or main partner of the project. Upon receipt of the application, the applicant will be contacted by email within a maximum of two working days, and if the identity and scientific competence of the applicant is confirmed (which can be verified by checking his/her IDs in international scientific networks such as ORCiD, Scopus), The data will be sent to him/her in the form of an Excel file and via email on the same day.

Comments