

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The effect of nursing interventions based on Wells scale results on the incidence of deep vein thrombosis in patients admitted to the intensive care unit

#### Protocol summary

##### Study aim

The aim of this study was to determine the effect of nursing interventions based on the results of Wells comparisons on the incidence of deep vein thrombosis in patients admitted to the intensive care unit. According to previous studies in Iran and the world, the assessment of the risk of patients at risk for deep vein thrombosis is based on a doctor's own judgment and experience, which puts these patients at risk of developing pulmonary embolism that could expose the lives of patients. It also increases the length of hospitalization and patient costs.

##### Design

In this study, 72 patients admitted to the intensive care unit with a study entry age range of 18 to 65 years of age with no prostate thrombosis and pulmonary embolism are selected. Participants were randomly assigned to two groups of intervention (36) and control group (36).

##### Settings and conduct

This study is a non-blind clinical trial without placebo, in which patients with a minimum of 10 days admission to the intensive care unit will be selected.

##### Participants/Inclusion and exclusion criteria

Patients aged between 18 and 65 years with no prostate thrombosis and pulmonary embolism will be excluded and will be excluded if they fail to cooperate or die.

##### Intervention groups

After entering the study, patients will be divided into two non-hazardous (less than 1) and at risk levels (grade 2 and more), deep vein thrombosis, and will be studied for 10 days, based on the Wells scoring scale. In the intervention group, according to the Wells scale risk assessment, in the non-risk group, nursing interventions such as exercise (flexion and dorsal flexion of the lower extremity), respiratory exercises, effective cough, and maintaining the lower extremity above the heart level will be performed. In the at-risk group, in addition to the

nursing interventions mentioned, the mechanical preventive measures (anti-embolism socks) and drug prevention (anaxaparin based on the prescribing dose of the physician) will be used. In the control group, patients will receive routine care according to the physician's instructions. Then, both interventional and control groups for the detection of deep vein thrombosis in the first, fifth and tenth days will be examined by the D-dimer test and Doppler sonography.

##### Main outcome variables

Patient evaluation can be beneficial by using a clinical predictive scale (Wells scale) for rapid identification of patients; Early identification of at-risk patients and nursing care can reduce mortality, hospitalization time, and patient costs.

#### General information

##### Reason for update

##### Acronym

DVT

##### IRCT registration information

IRCT registration number: **IRCT20170624034723N1**

Registration date: **2018-01-05, 1396/10/15**

Registration timing: **retrospective**

Last update: **2018-01-05, 1396/10/15**

Update count: **0**

##### Registration date

2018-01-05, 1396/10/15

##### Registrant information

##### Name

Morteza Habibi Moghadam

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 4232 1360

**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Ahvaz Jundishapur University of Medical Sciences and health Services

**Expected recruitment start date**

2017-07-23, 1396/05/01

**Expected recruitment end date**

2017-12-22, 1396/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of nursing interventions based on Wells scale results on the incidence of deep vein thrombosis in patients admitted to the intensive care unit

**Public title**

The effect of nursing interventions based on Wells scale results in the incidence of deep vein thrombosis

**Purpose**

Diagnostic

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

The age range is 18 to 65 years Patients with a minimum shelf-life of 10 days in Intensive Unit

**Exclusion criteria:**

Deep Vein Thrombosis or pulmonary embolism. take drugs that lead to blood coagulation, such as Tranexamic Acid. chronic disease that affects the treatment process, such as severe vascular disease, kidney failure. having chronic alcohol consumption history Pregnancy. In the event of any hemodynamic disorder (such as severe rhythm instability, septic shock and instability in blood pressure). Patients with coronary artery disease in the acute phase. Detect an imminent death by a doctor. Failure to co-operate with the patient or his supervisor.

**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: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants were randomly assigned and randomly divided into two intervention groups (36) and a control group (36) using a randomized design designed by a

statistic consultant.

**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 Committee of Ahvaz Jundishapur University of Medical Sciences

**Street address**

Ethics Committee, Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

61357-15749

**Approval date**

2017-07-23, 1396/05/01

**Ethics committee reference number**

IR.AJUMS.REC.1396.378

**Health conditions studied**

**1**

**Description of health condition studied**

Deep Vein Thrombosis

**ICD-10 code**

I82

**ICD-10 code description**

Formation of thrombosis in the deep veins

**Primary outcomes**

**1**

**Description**

Incidence of deep vein thrombosis

**Timepoint**

Days 1, 5, 10

**Method of measurement**

Wells scale, d-dimer, Doppler ultrasound

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

In the intervention group, patients who are on a Wells scale fall into an unprotected group. Nursing interventions include exercise (flexion and dorsiflexion of the lower limb flexion), respiratory exercises, effective cough, and maintaining lower limbs above the cardiac level. Patients who are considered to be at high risk of developing deep vein thrombosis based on the Wells scale, in addition to nursing interventions, will use mechanical preventive measures (anti-embolic socks) and drug prevention (Enoxaparin Sodium based on the prescribing dose of the physician).

#### Category

Prevention

### 2

#### Description

In the control group (n = 36) after the classification of patients according to Wells scale to two levels of no-risk (18 cases) and at high risk (18 cases), deep vein thrombosis involved patients with routine care interventions including: exercise (Respiratory exercises, effective cough, and lower extremity maintenance are higher than the heart rate, according to the instructions of the respective physician).

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Gonjavian Hospital

##### Full name of responsible person

Morteza Habibi Moghadam

##### Street address

Andimeshk Dezful Road, Dezful

##### City

Dezful

##### Province

Khouzestan

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64619-16118

##### Phone

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur

University of Medical Sciences

##### Full name of responsible person

Behzad Makmalzadeh

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Golestan st, Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences, Ahvaz

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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

Vice chancellor for research, Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

##### Full name of responsible person

Morteza Habibi Moghadam

##### Position

Master of Nursing Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Anesthesiology

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## Person responsible for scientific inquiries

### Contact

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Marzieh Asadizaker

**Position**

Phd of Nursing, Faculty Member

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Ph.D.

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## Person responsible for updating data

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**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

Anesthesiology

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

Undecided - It is not yet known if there will be 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**

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

**Data Dictionary**

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