

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Investigating the impact of using the navigation system on driving performance by simulation

#### Protocol summary

##### Study aim

Evaluating the impact of using the navigation system on driving performance by simulation

##### Design

Clinical trial with intervention and control group, two-way blind, The sample size of 40 people will be used to randomize and create random sequences of Ralloc Module in STATA software. Allocation concealment will be by use of matte sealed envelopes will be done.

##### Settings and conduct

This study is performed in the traffic laboratory of Road Accident Prevention Research Center of Tabriz University of Medical Sciences. A video camera or eye tracker will be used to record a person's visual performance during the execution of scenarios. Also, in order to eliminate the study, Determine the existence of an interaction between the use of the navigation and ability for continuous attention and divided attention in relation to driving performance participants will be given tests of ability divided attention, Continuous performance test, reaction time by the Vienna test system.

##### Participants/Inclusion and exclusion criteria

The study population in this study is healthy drivers who have driver's license and have at least two years of driving experience.

##### Intervention groups

Participants randomly drive in groups A and B with the simulator. Group A will drive first with navigation (intervention) and then without navigation (control) with simulator, and group B will drive first without navigation and then with navigation.

##### Main outcome variables

Performance indicators of people driving with and without the use of navigation; reaction time to pedestrian crossing; lateral deviation; exceeding the speed limit

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201018049066N1**

Registration date: **2020-11-01, 1399/08/11**

Registration timing: **prospective**

Last update: **2020-11-01, 1399/08/11**

Update count: **0**

##### Registration date

2020-11-01, 1399/08/11

##### Registrant information

##### Name

Esmat Saberi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6627 4605

##### Email address

esmat.saberi021@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-10, 1399/09/20

##### Expected recruitment end date

2021-03-10, 1399/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the impact of using the navigation system on driving performance by simulation

#### Public title

The impact of using the navigation system on driving performance by simulation

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

No problem with uncorrected vision and color blindness  
No simulator disease Do not take Analgesic and sleeping pills the night before the test No organ defects  
Volunteering to participate in the study At least two years of driving experience No Mental disease

##### Exclusion criteria:

Occurrence of any discomfort for the person during the study that prevents from continuing to cooperate or the person refuses to continue participating in the study for any reason. Individual incompatibility with the simulator during preparation

#### Age

From 20 years old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 40

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

In this study, 40 participants randomly drive in two groups A and B with a simulator. Group A will drive first with a navigation and then without a navigation with a simulator, and group B will drive first without a navigation and then with a navigation. Participants in the distance between the two modes (with and without a router) to control the learning effect and fatigue. They will rest for 5 minutes. The Ralloc Module will be used in STATA software to randomize and create random sequences. Allocation Concealment coverage will be done using opaque numbered envelopes

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Crossover

#### Other design features

### Secondary Ids

empty

### Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Azadi St., Golgasht St.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

کد پستی: 5165665931

#### Approval date

2020-09-07, 1399/06/17

#### Ethics committee reference number

IR.TBZMED.REC.1399.596

### Health conditions studied

### 1

#### Description of health condition studied

Use the navigation system while driving

#### ICD-10 code

#### ICD-10 code description

### Primary outcomes

### 1

#### Description

Reaction time to cross the pedestrian

#### Timepoint

Measure once while using the Navigation and once without using the Navigation

#### Method of measurement

Driving simulator system

### 2

#### Description

lateral deviation

#### Timepoint

Measure once while using the Navigation and once without using the Navigation

#### Method of measurement

Driving simulator system

### 3

#### Description

Exceeding the speed limit

#### Timepoint

Measure once while using the Navigation and once without using the Navigation

#### Method of measurement

Driving simulator system

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In order to determine the effect of using a router on driving performance, people randomly drive in groups A and B with a simulator. Group A They drive first with navigation(Intervention) and then without navigation(Control) with simulator, and group B first drives without navigation and then with navigation .Performance of people while driving in terms of variables of reaction time to events, lateral deviation, route navigation error and exceeding the speed limit will be recorded by the system.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tabriz Road Accident Prevention Research Center

##### Full name of responsible person

Dr. Homayoun Sadeghi Bazargani

##### Street address

Road Accident Prevention Research Center, Next to Shahrn Tower, Towards the Flight, Golshahr Square, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5167846311

##### Phone

+98 41 3380 0568

##### Email

tiscsc@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research, Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Hassan Aslani

##### Street address

Faculty of Health, Attar Neyshabouri St., Golgasht St., Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5165665931

##### Phone

+98 41 3335 7581

##### Email

research-vice@tbzmed.ac.ir

#### 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, Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Esmat Saberi

##### Position

Master student in Health and Traffic

##### Latest degree

Bachelor

##### Other areas of specialty/work

Health and Traffic

##### Street address

Faculty of Health, Attar Neyshabouri St., Golgasht St., Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5165665931

##### Phone

+98 41 3335 7582

##### Email

esmat.saberi021@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Yahya Rasoulzadeh

**Position**

Associate Professor of Occupational Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Health

**Street address**

Faculty of Health, Attar Neyshabouri St., Golgasht St.,  
Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614711

**Phone**

+98 41 3335 7581

**Email**

rasoulzadehy@tbzmed.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Esmat Saberi

**Position**

MSc student in Health and Traffic

**Latest degree**

Bachelor

**Other areas of specialty/work**

Health and Traffic

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**Email**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

This study is a master's thesis and its data is confidential.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available