

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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
 5165665931: کد پستی.
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

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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

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

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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, 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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Yahya Rasoulzadeh

Position

Associate Professor of Occupational Health

Latest degree

Ph.D.

Other areas of specialty/work

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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

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

Tabriz University of Medical Sciences

Full name of responsible person

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Position

MSc student in Health and Traffic

Latest degree

Bachelor

Other areas of specialty/work

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