Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Isocapnic hyperventilation (iHV) on detoxification of methanol poisoned patients: A pilot study

Protocol summary

Study aim
Our main goal is to evaluate methanol kinetics (and formate kinetics) during iHV when toxicity is being prevented by fomepizole blockade of ADH.

Design
This prospective (phase I) study, will be conducted on 30 methanol-poisoned patients referring to the toxicological emergency department of Loghman Hakim hospital in 2022.

Settings and conduct
Setting: Loghman Hakim Hospital Intervention: Standard of care with Fomepizole plus iHV device treatment Rescue therapy: Haemodialysis at investigator's discretion

Participants/Inclusion and exclusion criteria
Inclusion: Adult patients, men & women diagnosed with methanol poisoning S-metOH ≥ 50mg/dL pH ≥ 7.0, correctable by bicarbonate infusion no visual disturbances Exclusion: Acidosis requiring haemodialysis Comatose patients

Intervention groups
Methanol toxicity patients who have a serum methanol level ≥ 50mg/dL

Main outcome variables
Definition of methanol and formate elimination kinetics, including physiologically based pharmacokinetic (PBPK) modeling, when iHV is utilized

General information

Reason for update

Acronym
iHV

IRCT registration information
IRCT registration number: **IRCT20120629010133N5**
Registration date: **2022-09-10, 1401/06/19**
Registration timing: **prospective**
Last update: **2023-12-03, 1402/09/12**
Update count: **1**

Registration date
2022-09-10, 1401/06/19

Registrant information

Name
Hossein Hassanian-Moghaddam

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2023-12-22, 1402/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Isocapnic hyperventilation (iHV) on detoxification of methanol poisoned patients: A pilot study

Public title
The effect of increasing pulmonary ventilation in methanol poisoning

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients, men & women diagnosed with methanol poisoning Serum methanol ≥ 50mg/dL pH ≥ 7.0, correctable by bicarbonate infusion no visual disturbances

Exclusion criteria:

Acidosis requiring haemodialysis Comatose patients

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **14**

Arterial blood gas, Serum Methanol Level, Serum Formate Level

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Loghman-Hakim Hospital, Kamali Ave, South Karegar

City

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Province

Tehran

Postal code

13336

Approval date

2022-07-24, 1401/05/02

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.214

Health conditions studied

1

Description of health condition studied

Toxic alcohols

ICD-10 code

T51.1

ICD-10 code description

Toxic effect of methanol

Primary outcomes

1

Description

Change in methanol elimination kinetics (half-life and estimated clearance) when iHV is utilized

Timepoint

Hourly before intervention, and 1-2 hourly post intervention till 24 hours

Method of measurement

Measuring serum/urine methanol, formate

Secondary outcomes

1

Description

Score of iHV machine tolerability

Timepoint

Hourly

Method of measurement

Qualitative interview

2

Description

Score of feasibility of iHV machine

Timepoint

Hourly

Method of measurement

Likert's scale

3

Description

Implementation of fomepizole in Iran

Timepoint

End of trial

Method of measurement

Likert's scale

4

Description

Length of ICU- and hospital stay during treatment with iHV

Timepoint

End of trial

Method of measurement

Time frame of hospital stay

5

Description
Death
Timepoint
End of trial
Method of measurement
Yes or No

6

Description
Need for haemodialysis
Timepoint
hourly
Method of measurement
Yes or No

7

Description
Adverse Events
Timepoint
hourly
Method of measurement
Yes or No

Intervention groups

1

Description
Intervention group: iHV. The concept of isocapnic hyperventilation (iHV) allows the person to hyperventilate while keeping the CO2 within normal limits at the same time. The ClearMate (Thornhill Research Inc., Canada) adds CO2 to the inspired air to compensate to the increased loss induced by the increased minute ventilation. This means that hyperventilation can occur, and a wash-out of volatile substances such as methanol will happen without disrupting the important CO2 balance. iHV increases the elimination of methanol to the extent that it could replace hemodialysis for elimination purposes when hemodialysis is not required for the correction of acidosis. Likewise, Alcohol Dehydrogenase (ADH), the responsible enzyme for methanol metabolization and further acidosis is completely blocked by Fomepizole during the intervention. Methanol serum level will be measured every 2 hours and iHV will be stopped if it is <5 mmol.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada-e Tajrish Hospital-Tehran
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2

Recruitment center
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Sponsors / Funding sources

1

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Grant name
The iHV-Met study
Grant code / Reference number
32499
Is the source of funding the same sponsor organization/entity?
No

Title of funding source
University in Oslo
Proportion provided by this source
95
Public or private sector
Public
Domestic or foreign origin
Foreign
Category of foreign source of funding
Sponsor: country of origin
Country of origin
NO
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Position
Assiciate Professor
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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
Only main outcomes will be shared
When the data will become available and for how long
Sharing at the time of publication in a scientific journal
To whom data/document is available

Only for researchrs

Under which criteria data/document could be used

It would be defined later

From where data/document is obtainable

Via email

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

Having a reasonable request, it takes almost one month

Comments

No