

A dry month: a study on the effects of one month alcohol abstinence on health

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Evaluate effects of one month alcohol abstinence in a healthy population of moderate drinkers.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42437

Source

ToetsingOnline

Brief title

A dry month

Condition

- Other condition
- Hepatic and hepatobiliary disorders
- Lifestyle issues

Synonym

harmful effects of moderate alcohol intake on health

Health condition

lichamelijke en psychische gezondheid

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: alcohol, fatty liver, mental health, physical health

Outcome measures

Primary outcome

Proportional decrease in liver steatosis after intervention

Secondary outcome

Proportional decrease in liver steatosis at week 8

Proportional decrease in liver stiffness at week 4, 8

Proportional decrease in body weight, fatpercentage, bloodpressure at week 4,8

Proportional decrease in glucose and cholesterol spectrum at week 4,8

Proportional decrease in liverenzymes at week 4,8

Proportional improvement in sleep quality at week 4,8

Proportional improvement in ability to concentrate at week 4,8

Proportional improvement in ability to enjoy oneself at week 4,8

Proportional change in lifestyle at week 4,8

Proportional decrease in alcohol intake at week 8

Difference between intervention and controlgroup for all above listed variables

at week 0,4,8

Study description

Background summary

Excessive alcohol use is a growing problem in the Western world. Alcohol is processed in the liver. Therefore the liver can be damaged. This damage is an effect of the direct toxic effect of alcohol on the liver cells (=hepatitis).

Furthermore alcohol leads to fat accumulation in the liver (=steatosis). This fat also leads to inflammation. After prolonged damage scarring of the liver can occur (=fibrosis).

Other processes in the body are also negatively influenced by excessive alcohol intake. It can lead to obesity, cardiovascular disease, diabetes, and mental problems. If alcohol intake is ceased these effects are reversible with many people.

In people with moderate alcohol intake (short) abstinence of alcohol intake may also lead to positive health effects, as shown in recent cohorts (ref 1,2).

The sustainability of these effects has not yet been thoroughly studied.

References

1.

<https://www.newscientist.com/article/mg22129502-600-our-liver-vacation-is-a-dry-january-really-worth-it/>

2. <http://onlinelibrary.wiley.com/doi/10.1002/hep.28184/full> Abstract 113; AASLD 2015

Study objective

Evaluate effects of one month alcohol abstinence in a healthy population of moderate drinkers.

Study design

Prospective cohort study of 10 healthy volunteers that undergo intervention (one month alcohol abstinence) with control group of 10 healthy volunteers who never consume alcohol. All volunteers undergo several investigations before intervention (t=0), after intervention (t=4) and after additional follow-up of 4 weeks (t=8).

Variables:

- body weight, fat percentage, blood pressure
- Liver steatosis measurement (CAUS)
- Liver stiffness (Fibroscan)
- Glucose, HbA1C, plasma insulin, C-peptide
- Cholesterol spectrum + triglycerides
- Liver enzymes
- CDT
- hemocytometry
- iron, hepcidin, ferritin, transferrin saturation, C-reactive protein
- Na, K, Creat, U, Mg
- TSH, FT4

Questionnaires:

-Alcohol intake: quantification, AUDIT-C, CAGE

-Evaluation lifestyle: SLIQ

Cognitive function:

-Quality of sleep: PSQI

-Concentration

-Self-assessment ability to enjoy oneself: SHAPS

Intervention

one month alcohol abstinence

Study burden and risks

Three visits of 1-2 hours to hospital for tests. Discomfort from blood withdrawal (pain, hematoma).

Possibility of unexpected findings from tests that require medical attention.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

above 18 years

mentally competent

Exclusion criteria

-pregnant or lactating

-known liver disease

Study design

Design

Study type: Interventional

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-11-2016

Enrollment: 20

Type: Actual

Ethics review

Approved WMO	
Date:	11-07-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL56238.091.15