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Effects of sleep deprivation and low blood alcohol on driving capacities in young people

Submission date
31/01/2014

Recruitment status
No longer recruiting

Registration date
10/02/2014

Overall study status
Completed

Last Edited
12/02/2021

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Driving while sleep deprived and after alcohol consumption are frequently suspected in road traffic crashes among young drivers. The effects of sleep deprivation on driving can be increased even at low legal levels of blood alcohol. This study aims to clarify how and to what degree sleep deprivation combined with low, legal levels of alcohol consumption influences driving in young drivers.

Who can participate?
Male and female drivers aged 18-25 years and 30-34 years.

What does the study involve?
The effects of combined sleep deprivation and low legal alcohol levels on simulated driving performance will be compared to either of these conditions alone.

Participants are randomly allocated to one of four groups:
1. No alcohol intake, no partial sleep deprivation
2. Alcohol intake, no partial sleep deprivation
3. No alcohol intake, partial sleep deprivation (1 hour less of sleep/night over a one-week period)
4. Alcohol intake, partial sleep deprivation (1 hour less of sleep/night over a one-week period)

What are the possible benefits and risks of participating?
Participants receive a maximum compensation of 250 Canadian dollars for their time and transport.
About 5% of participants may suffer simulation sickness that includes dizziness, nausea and vomiting. We screen for simulation sickness during a driving simulation practice session lasting about 10 minutes. We advise participants to reduce or avoid driving during their participation. To avoid any risks following alcohol administration, participants
are advised to leave the laboratory only after their blood alcohol drops to 0%. Taxis are made available to participants if they feel fatigued following the experimental sessions.

Where is the study run from?
Douglas Mental Health University Institute Research Centre in Montreal, Canada.

When is the study starting and how long is it expected to run for?
The study will start recruiting participants in February 2014 and will run until March 2016.

Who is funding the study?
Canadian Institutes of Health Research (CIHR) and a consortium made up of Quebec Society & Culture Research Foundation (Fonds de Recherche du Québec Société et Culture - FQRSC), Quebec Motorcar Insurance Company (Société de lAssurance Automobile de Québec - SAAQ) and Quebec Health Research Foundation (Fonds de Recherche du Québec Santé - FRSQ), Canada.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Canadian Institutes of Health Research MOP-123346

Study information

Scientific Title
Effects of sleep deprivation and low blood alcohol on executive functions in young drivers: a randomized controlled trial

Study objectives
To compare the effects of cumulative sleep deprivation and legal blood alcohol levels on the safe driving capacities of young people.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Douglas Mental Health University Institute Review Ethics Board, 17/01/2014, ref. REB#12/18

Study design
Randomized controlled trial - double blinded for sleep deprivation induction and alcohol dose

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Injury prevention, driving while impaired by alcohol and/or sleep deprived

Interventions
The participants are randomised to one of four conditions.
1. No alcohol intake, no partial sleep deprivation
2. Alcohol intake [blood alcohol concentration (BAC) = 0.03%], no partial sleep deprivation
3. No alcohol, partial sleep deprivation (1 hour less of sleep/night over a one week period)
4. Alcohol (BAC = 0.03%), partial sleep deprivation (1 hour less of sleep/night over a one week period)
One follow-up session is involved for measurement of simulated driving performance.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Driving performance on the driving simulator measured at intake and one week following randomization to condition and the partial sleep deprivation induction protocol.

Secondary outcome measures
Performance on neuropsychological executive function tasks

Overall study start date
01/02/2014

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Male and female drivers aged 18-25 years and 30-34 years, having drunk alcohol in the past 6 months
2. Having driven in the past 3 months
3. Medication-free (except contraceptives for females)
4. Usually sleeps during regular night-time hours

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
34 Years

Sex
Both

Target number of participants
300

Total final enrolment
93

Key exclusion criteria
1. Attention-deficit hyperactivity disorder diagnosis
2. Signs of alcohol dependence
3. Signs of drug dependence
4. Sleep problems
5. Pregnancy or breastfeeding

Date of first enrolment
01/02/2014

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
Canada

Study participating centre
Douglas Mental Health University Institute Research Centre
Montreal
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Sponsor information

Organisation
Douglas Mental Health University Institute Research Centre (Canada)

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Sponsor type
Research organisation

Website
http://www.douglas.qc.ca/page/administration

ROR
https://ror.org/05dk2r620

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada)

Alternative Name(s)

Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Consortium made up of Quebec Society & Culture Research Foundation (Fonds de Recherche du Québec Société et Culture - FQRSC) + Quebec Motorcar Insurance Company (Société de l Assurance Automobile de Québec - SAAQ) + Quebec Health Research Foundation (Fonds de Recherche du Québec Santé - FRSQ) (Canada)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2019	12/02/2021	Yes	No