Effects of opioid analgesics on driving ability of pain patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29168

Source
Nationaal Trial Register

Health condition

Chronic non-cancer pain, Opioids, Driving ability

Sponsors and support

Primary sponsor: Federal Highway Research Institute (BASt)
Brüderstraße 53
51427 Bergisch Gladbach
Germany
Source(s) of monetary or material Support: European Commission within the 6th Framework Programme; this clinical trial is part of the DRUID project (www.druid-project.eu)

Intervention

Outcome measures

Primary outcome

SDLP (Standard Deviation of Lateral Position = a measure of road tracking error while driving on a primary highway; measures the ammount of weaving).

Secondary outcome

1. Performance scores of test of driving related skills;

2. P300 (amplitude, latency);

3. Reaction time.

Study description

Background summary

This study is aiming at assessing the impairing effects of long term treatment of chronic pain with opioid analgesics on driving ability. A group of 30 patients suffering from chronic non-malignant pain will be enrolled into the study. To meet the inclusion criteria, patients must be already treated by their attending physician by one of the following analgesics: transdermal Fentanyl, transdermal Buprenorphine, retarded Oxycodone, retarded Oxycodon (combined with Naloxone), retarded Hdromorphone, retarded Morphine, retarded Tramadol or retarded Tilidin (combined with Naloxone). There is no study related change in substance, dosage or way of administration of opioid analgesics done. The performance of the patients will be compared to the performance of 30 matched healthy volunteers driving sober as well as under the influence of alcohol (0.5 per mille).
Performance assessments will consist of driving tests conducted on a public highway near Maastricht (Netherlands) by the Faculty of Psychology and Neuroscience of Maastricht University and of computerized laboratory tests of driving related skills which are conducted at the Pain Outpatient Department of the University Hospital of Cologne.
The driving test applied is a standardized procedure frequently used within the field of research on the impairing effects of psychoactive medical and illegal drugs. It has proven to be sensitive to drugs with sedating effects. The practical outcome of the study is to determine whether pain patients under long-term treatment are impaired in actual driving.

Study objective

N/A

Study design

The highway driving test is used to measure SDLP. The Vienna Test System is used to measure skills related to driving. Both measures are conducted once.

Intervention

1. Driving test on a public highway;

2. Computer based test of driving related skills;

3. Taking of blood sample;

4. EEG measure.

The performance of the patients will be compared to the performance of 30 matched healthy volunteers driving sober as well as under the influence of alcohol (0.5 per mille).

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Eligibility criteria

Inclusion criteria

1. Age: 30 to 65;

2. Body weight within 16-35 according to body mass index (BMI);

3. Vision normal or corrected to normal;

4. Valid driver’s license for passenger cars;

5. Kilometres travelled per year: at least 2.000 km per year during preceding 12 month;

6. Driving on a regular basis: at least once per week;

7. Ability to drive a passenger car with manual transmission;

8. Treatment for at least four weeks with:

A. Transdermal Fentanyl (e.g. Durogesic Smat®) = 12 µg/h, or;

B. Transdermal Buprenorphine (e.g. Transtec®) = 10µg/h, or;

C. Retarded Oxycodone (e.g. Oxygesic®) = 10 mg/day, or;

D. Retarded Oxycodone combined with Naloxone (z.B. Targin ®) = 10 mg/day, or;

E. Retarded Hydromorphone (z.B. Palladon®, Jurnista®) = 4 mg /day, or;

F. Retarded Morphine (z.B. MST®) = 20 mg/day, or;

G. Retarded Tramadol (z.B. Tramal long®) = 100 mg/day, or;

H. Retarded Tilidin combined with Naloxone (z.B. Valoron N ®) = 100 mg/day.

9. No dose change within the preceding 14 days;

10. Co-medication with NSAID and/or anticonvulsants and/or antidepressants on a stable dose within the preceding 14 days.

Exclusion criteria

1. Subjects who fail to meet any of the inclusion criteria;

2. Persons who are imprisoned or are detained in a health mental institution by court or official order;

3. Malignant disease;

4. Severe disabilities that are expected to interfere with computerized testing or car driving;

5. Expected inability to drive the experimental car safely or to complete computerized testing or endangerment of being overstrained during the driving test or during computerized testing according to the estimation of the physician accomplishing the medical check up;

6. Psychological or psychiatric disorders or severe physical disorders (history or current evidence of severe physical or mental disorders, serious gastrointestinal, hepatic, renal, cardiovascular or neurological disorders or severe allergies) that may interfere with participation in computerized testing or driving test;

7. Subjects with alcohol or drug abuse or dependency;

8. Unwillingness or inability to abstain from consumption of alcohol, psychoactive medication or drugs within 24 hours prior to the assessment day (urine drug screening, alcohol breath analyzer);

9. Excessive drinkers (more than 28 glasses of alcohol containing beverages per week);

10. Inability or unwillingness to abstain from smoking for the duration of the driving test or the computer based test;

11. Regular intake of Benzodiazepines (= 4 times per week);

12. Intake of Benzodiazepines within 2 days before assessment days;

13. Regular intake of barbiturates (> 3 times per week) as well as intake of barbiturates within 2 days before the assessment days;

14. Daily intake of antidepressants in higher dosage (Amitryptilin > 75mg, Doxepin > 75mg, Imipramin > 75mg, Trazodon > 100mg, Sertralin > 50mg, Fluoxetin > 20mg, Fluvoxamin >75mg, Duloxetin > 120mg, Venlafaxin > 225mg, Citalopram > 10mg);

15. Daily intake of anticonvulsant in higher dosage (Carbamazepin > 1200mg, Oxcarbazepin >1800mg, Gabapentin >2400mg, Pregabalin >600mg);

16. Intake of MAO inhibitors;

17. Regular intake of un-retarded opioids (= 7 times per week) or intake of un-retarded opioids within 2 days prior to assessment and on the assessment days;

18. Regular intake of antihistamines;

19. Inability to communicate meaningfully with the study staff (insufficient language skills);

20. Participation in another study within 30 days before enrolment to this study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-11-2009
Application type:	First submission

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
NTR-new	NL1976
NTR-old	NTR2093
Other	EudraCT number : 2009-011774-15
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A