Reliability of the *on-site test* for gamma-hydroxybutyric acid (GHB) and the clinical relevance of this test: On-site DrugCheck® GHB Single Test * Express Diagnostics®

Published: 31-12-2015
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Determining the sensitivity and specificity of the on-site GHB test.

Ethical review	Not approved
Status	Will not start
Health condition type	Exposures, chemical injuries and poisoning
Study type	Observational invasive

Summary

ID

NL-OMON42350

Source
ToetsingOnline

Brief title
Reliability and clinical relevance of an on-site GHB test.

Condition

- Exposures, chemical injuries and poisoning

Synonym
Diagnosis intake GHB, identification intake GHB.

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis

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

Intervention

Keyword: Emergency department, GHB, GHB intoxication, on-site test

Outcome measures

Primary outcome

Determining the sensitivity and specificity of the on-site GHB test by

comparing the results with the HPLC-MS/MS results.

Secondary outcome

1. Cinical relevance is determined based on a questionnaire filled in by the

doctor, containing questions about the influence of the results of the test

regarding the treatment.

2. Alcohol promillages are measured in blood to rule out possible interference

of alcohol on the test.

3. Urine samples with a fals-postive on-site testresults are subjected to a

urine toxscreen to determine interference with other drugs of abuse.

4. The sensitivity and specificity of an immunoassaytechnique for the

measurement of GHB-concentrations in urine will be investigated.

Study description

Background summary

Currently it's not possible to carry out a quick measurement of the concentration GHB in the urine or blood when a patient presents with a reduced consciousness at the emergency department. By the time analysis of GHB in urine or blood at the clinical pharmaceutical laboratory is completed, the patient has awoken out of the GHB-induced coma. Therefore no added value is stated for the analysis in the clinical pharmaceutical laboratory in terms of diagnosis

and treatment.

In some situations the quick measurement of GHB concentrations is very useful to figure out possible intake of GHB. For example for patients with trauma or coma due to a mixed intoxication the test might be useful to determine the right treatment. Plausible result might be a reduce in the amount of CTs of the cerebrum and other added diagnostics.

Study objective

Determining the sensitivity and specificity of the on-site GHB test.

Study design

Urine and blood is conform standard care taken from patients with a reduced consciousness or a possible GHB intoxication at the emergency department. An extra 5 ml blood is taken for this study. Patients who claim to have taken in GHB without reduced consiousness are asked to give urine and blood; this is not standard practice. A short questionnaire is filled in by the doctor, containing questions about the influence of the results of the test regarding the treatment. GHB-concentrations are measured in the urine with the on-site GHB test and a validated HPLC-MS/MS method to determine the sensitivity and specificity of the on-site test. Alcohol promillages are measured in blood to rule out possible interference of alcohol on the test. Urine samples with a fals-postive on-site testresults are subjected to a urine toxscreen to determine interference with other drugs of abuse. Also, the sensitivity and specificity of an immunoassaytechnique for the measurement of GHB-concentrations in urine will be investigated.

Study burden and risks

Risk associated with participation is low. Normally, blood and urine is taken in most situations of patients with reduces consciousness.

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

Patients with age 18-45 year with reduced consciousness GCS* 8
Patients with age 18-45 year without reduced consciousness who declare to have taken in GHB.

Exclusion criteria

Age < 18 or > 45 year

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	910
Type:	Anticipated

Ethics review

Not approved

Date:	31-12-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL55233.100.15