

# The incidence of hyponatremia in people using MDMA

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To study the incidence of (mild) acute hyponatremia in ecstasy users at rave parties.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON34993

### Source

ToetsingOnline

### Brief title

XTC and hyponatremia

### Condition

- Other condition

### Synonym

hyponatriemia, low levels of salt in the blood, low sodium levels in blood, water poisoning

### Health condition

elektrolyten stoornissen bij drugs gebruik

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Unity Amsterdam en Educare Groningen;ieder 1000 euro.

## Intervention

**Keyword:** ecstasy/XTC, hyponatremia, incidence, MDMA

## Outcome measures

### Primary outcome

- sodium levels in blood (through point of care measurement)
- use of drugs (through dipstick of urine)

### Secondary outcome

not applicable

## Study description

### Background summary

Numerous case-reports have been published on fatal cases of hyponatremia in people using ecstasy. We think that these cases are just the tip of the iceberg. Probably a lot of mild cases of hyponatremia occur in ecstasy users at rave parties, giving no to mild symptoms. No research has been done on this topic so far.

### Study objective

To study the incidence of (mild) acute hyponatremia in ecstasy users at rave parties.

### Study design

Setting:

Rave party \*chill out\* space. From 03:30 am till the end.

People will be informed and asked to cooperate anonymously in the research on saltlevels in blood of visitors at rave-parties.

General measurements:

- ambient temperature
- time at contact

Questionnaire:

- Time party admission
- Age
- Sex
- Use of MDMA, if yes, when, dose en amount if known.
- Other drugs
- Alcohol, amount
- Other drinks, amount
- Food, when and what
- Smoking

Measurements:

- General: weight, length
- Point of care: sodium
- Urine: distick on drug use

All materials will be destroyed the same night.

Reward: icecream

### **Study burden and risks**

The visitors at a rave party will be asked to participate in the study in the chill out room. They will be asked to answer 10 short questions. Also they will receive a vingerprick to determine the sodium level in the blood through the point of care device. And last they will be asked to hand in urine wich will be tested on drugs. This will all be dealt with in an anonymous manner.

## **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

rave-visitors, at least 50 visitors that used MDMA and 50 non-users will be tested

### Exclusion criteria

- under 18
- less than 2 hours at the party
- aversion against blood

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-04-2010
Enrollment:	100
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	09-09-2010
Application type:	First submission
Review commission:	METC NedMec

## 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	NL29997.041.10