# Co-prescribed heroin and methadone supplemented with with contingency management:
# A randomized controlled trial.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON24738

**Source**
NTR

**Health condition**

heroin dependency
cocaine
addiction
heroin-assisted treatment
contingency managemen

heroïne-afhankelijkheid
cocaïne
verslaving
behandeling met heroïne op medisch voorschrift
contingentie management

### Sponsors and support

**Primary sponsor:** Central Committee on the Treatment of Heroin Addicts (CCBH), Utrecht University Medical Center
**Source(s) of monetary or material Support:** Ministry of Health, Welfare and Sports, the Netherlands

## Intervention

## Outcome measures

### Primary outcome

The primary outcome measure will be the maximum number of consecutive weeks of cocaine metabolite-free urine samples during the first six months of the trial.

### Secondary outcome

Secondary outcome measures include (1) the percentage of responders at the month 6 time-point of the RCT-phase, in terms of the dichotomous multi-domain outcome index (improvements in physical and mental health and social functioning), which has been– and still is – used in the ongoing heroin study, (2) the number of cocaine metabolite-free urine samples during the trial period, (3) the percentage of patients with cocaine-free urine samples for at least 8, 12, and 16 consecutive weeks during the trial period, and (4) treatment retention.

# Study description

### Study objective

We propose to evaluate the beneficial effects of adding a contingengy management (CM) intervention, aimed at a reduction of cocaine consumption, to the current heroin-assisted treatment. This intervention – combined heroin-assisted treatment plus CM – will be compared to heroin-assisted treatment alone in a study population of chronic, treatment-resistant heroin dependent patients. The study questions are:

1. What is the effectiveness – in terms of reduced cocaine consumption and in terms of improvements in the areas of health and social functioning – of six months of ongoing heroin-assisted treatment plus contingency management, compared to six months of ongoing heroin-assisted treatment alone, in chronic, treatment-resistant heroin dependent patients?

2. What is the effect – in terms of cocaine consumption and in terms of health and social functioning – of terminating the contingency management intervention after six months?

3. What is the cost-utility of heroin-assisted treatment plus contingency management, compared to heroin-assisted treatment alone?

### Study design

The primary timepoint is 6 months after the start of the experimental study phase.

The secondary timepoint is 12 months after the start of the experimental study pahse (at the end of the 6 months naturalistic follow-up phase).

**Intervention**

Control group: Heroin-assisted treatment alone.

Subjects assigned to heroin-assisted treatment alone will receive a treatment offer of injectable or inhalable heroin (maximum of 400 mg per prescription and 1,000 mg per day) in combination with oral methadone. The co-prescribed heroin and methadone have to be used in the treatment center, under the supervision of the treatment-staff.

Experimental group: Heroin-assisted treatment plus contingency management.
Subjects assigned to heroin-assisted treatment plus CM will receive the same treatment offer as those in the heroin-assisted treatment alone condition, but with the addition of monetary vouchers for each cocaine-negative urine sample. The voucher value will be based upon an escalating schedule, with a reset after a cocaine-positive urine sample. The monetary vouchers obtained during the trial have to be spend on personal care or improvement of the (physical, mental or social) health status, after consent of the treatment staff.

## Contacts

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## Eligibility criteria

## Inclusion criteria

1. Treatment-resistant heroin dependency, as indicated by:

a. a history of heroin dependency (DSM-IV) of at least five years;

b. a minimum dose level of 50 mg (inhaling heroin) or 60 mg (injecting heroin) of methadone per day for an uninterrupted period of at least four weeks in the previous five years;

c. in the previous year registered in a methadone program, and during the previous six months in regular contact with the methadone program;

d. chronic heroin addiction and unsuccessfully treated in methadone maintenance treatment;

e. daily or nearly daily use of illicit heroin;

f. poor physical, and/or mental, and/or social functioning.

2. Clinically relevant cocaine use, as indicated by:

a. at least one cocaine-positive urine sample during the 4-8 weeks qualification period prior to the start of the heroin-assisted treatment, and

b. at least four days of cocaine use in the month preceding the start of the heroin-assisted treatment, according to self-report, and

c. at least two cocaine-positive urine samples in the month preceding the start of the experimental or control treatment.
During this month, a total of 12 urine samples will be requested, of which a minimum of 10 samples must be provided by the patient, and

d. at least four days of cocaine use in the month preceding the start of the experimental or control treatment, according to self-report.

3. Heroin is used through intravenous injection or inhalation.

4. At least 25 years old.

5. Citizen or legal resident in the Netherlands.

6. Registered as a resident in the city area of the treatment site for at least three years.

7. Willing and able to attend the treatment site for the required study assessments and other procedures.

8. Willing to attend the treatment site at least three days a week.

9. Written informed consent.

### Exclusion criteria

1. Not meeting all inclusion criteria.

2. Severe medical, psychiatric or psychosocial problems which constitute a contra-indication for participation.

3. Severe medical, psychiatric or psychosocial problems which may interfere with the conduct of the study.

4. A history of aggressive behavior which is expected to interfere with the conduct of the study and/or the participation in the study of other subjects.

5. Pregnancy or continued lactation, or desire to become pregnant in the near future.

6. Unwilling to attend the treatment site for the required assessments.

7. The heroin dependency is of secondary importance compared to an existing non-opiate dependency.

8. The patient is unwilling to use the prescribed heroin in the treatment site.

9. A period of voluntary heroin abstinence of at least two months in the previous year.

10. Patients requiring a dose of prescribed heroin exceeding 1000 mg per day.

11. Patients unable to understand the Dutch language.

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-04-2006 |
| Enrollment: | 200 |
| Type: | Actual |

## Ethics review

Positive opinion

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|---|---|
| Date: | 01-09-2014 |
| 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 | NL4560 |
| NTR-old | NTR4728 |
| Other | : CCMO05.2182/MA/P05.0820C |

## Study results