# Applying Mysimba in patients with weight regain after bariatric surgery

Published: 07-03-2022
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This study has been transitioned to CTIS with ID 2024-516645-39-01 check the CTIS register for the current data. The primary objective is to study the effect of naltrexone/bupropion in combination with the BOT module on successful weight loss(>5...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON54284

**Source**
ToetsingOnline

**Brief title**
AMPWR

### Condition

- Other condition
- Appetite and general nutritional disorders

**Synonym**
extreme overweight, Obesity

**Health condition**

Obesitas

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Zuyderland Medisch Centrum
**Source(s) of monetary or material Support:** bedrijf

## Intervention

**Keyword:** Bariatric Surgery, Naltrexone/bupropion, Obesity, Weight regain

## Outcome measures

### Primary outcome

The primary objective is to study the effect of naltrexone/bupropion(Mysimba) in combination with the BOT module compared to the regular BOT module for 22 weeks, the duration of the regular BOT, on weight loss in patients with weight regain after bariatric surgery.

### Secondary outcome

The secondary objectives are to describe the persistence of therapy of Mysimba after bariatric surgery; to study the used daily dose of Mysimba in patients after bariatric surgery; to evaluate eating behaviour in patient with weight regain after bariatric surgery who used Mysimba compared to patients on the regular module via the YFAS 2.0 questionair; to study adverse effects of Mysimba; to monitor and compare weight loss up to 12 months after the start of Mysimba in both study groups.

Tertiary objective(s):

These are the tertiary objectives:

a) To study bupropion and hydroxybupropion absorption/exposure by measuring steady-state serum levels in bariatric and compare these with steady-state

serum levels in obese patients on Mysimba therapy who did not undergo bariatric surgery

b) to correlate bupropion and hydroxybupropion steady-state serum levels with effectiveness of Mysimba

c) to determine the therapeutic range of bupropion and hydroxybupropion plasma levels in bariatric and obese patients on Mysimba.

# Study description

### Background summary

Although bariatric surgery is currently the most effective treatment for morbid obesity, weight regain occurs in 16-37% of the patients (1). Weight regain is not regularly treated with antiobesity medications (AOMs).
Mysimba (Contrave in US) is a AOM, it is a combination of naltrexone hydrochloride extended release and bupropion hydrochloride extended release for the treatment of obesity, and is used with lifestyle modification. Bupropion is a mild reuptake inhibitor of dopamine and norepinephrine. Naltrexone, an opioid antagonist has minimum effect on weight loss on its own. Naltrexone is thought to block the inhibitory effects of opioid receptors activated by the β-endorphin released in the hypothalamus that stimulates feeding, thus allowing the inhibitory effects of α-melanocyte stimulating hormone to reduce food intake. In patients with obesity usage of Naltrexone/Bupropion (NB) results in up to 8.2% weight loss (2). There is some evidence that also in bariatric patients with weight regain NB leads to additional weight loss (3, 4).
At the Nederlandse Obesitas Kliniek (NOK) weight regain at follow-up is currently treated with the Back on Track (BOT) program. The BOT program is an extra intervention our clinic provides for the patients who have weight regain after surgery, this is part of our standard care program.

### Study objective

This study has been transitioned to CTIS with ID 2024-516645-39-01 check the CTIS register for the current data.

The primary objective is to study the effect of naltrexone/bupropion in combination with the BOT module on successful weight loss(>5% weight loss) after 22 weeks in patients with weight regain after bariatric surgery, compared

to the regular BOT module.

### Study design

Randomized trail and cohort study

### Intervention

Adding Mysimba to the BOT program of the Nederlandse Obesitas Kliniek(NOK) and one-time venapuncture

### Study burden and risks

The burden of participation consists of extra usage of medication which patients have to administer orally on a daily basis. There will be no extra consultations to prevent that the medication group will have more guidance during the BOT programme. The risks consist of gastrointestinal side effects, anxiety, insomnia, and neurological side effects such as headache, dizziness, tremor, dysgeusia, lethargy, vertigo and tinnitus. (See SPC paragraph 4.8 for further explanation) It will be one of the first times Mysimba will be used in patients post-bariatric surgery, therefore the precise side effects are not known but assumed to be similar to previous studies. The benefits are possible better weight loss results compared to the regular BOT module.
There will also be a one-time venipuncture at patients randomised in the Mysimba group and at patients without bariatric surgery (=control cohort).

## 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

To be eligible to participate in this study, a subject must meet all of the following criteria:
• Patient is >=18 and <75 years old
• BMI before surgery was >= 35,0 kg/m2
• Patient has undergone a primary banded/non-banded Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (SG)
• Gaining more than 5% weight after reaching plateau phase of lowest weight

To be eligible to participate in the control patient cohort for measuring bupropion and hydroxybupropion serum levels a subject must meet all of the following criteria:
• Patient is >=18 and <75 years old
• Patient is obese (BMI > 30 kg/m2)
• Patient on successful Mysimba steady maintenance dose

## Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Anatomical or surgical abnormalities for which revisional surgery is indicated.
• Use of the following medication Monoamino-oxidase inbibitors (MAO), selective serotonin reuptake inhibitor (SSRI), Tricyclic antidepressants (TCA), haloperidol, risperidone, opioids, antiarrhythmics, betablockers, antiviral medication (HIV)
• Pregnancy or breastfeeding
• Patients suffering from:

o unregulated hypertension
o a tumour in the central nervous system
o severe liver failure
o end stage kidney failure
• Patients suffering from or with a history of insults
• Patients with a history of:
o bipolar disease
o bulimia or anorexia nervosa
• Patients withdrawing from alcohol or benzodiazepines
• Patients who are not able to understand the informed consent form and patient information.

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Treatment

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 21-03-2023 |
| Enrollment: | 160 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Contrave |
| Generic name: | naltrexone/bupropion |
| Registration: | Yes - NL intended use |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 07-03-2022 |
| Application type: | First submission |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |
| Approved WMO Date: | 26-06-2022 |
| Application type: | Amendment |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |
| Approved WMO Date: | 03-10-2022 |
| Application type: | Amendment |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |
| Approved WMO Date: | 06-03-2023 |
| Application type: | Amendment |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |
| Approved WMO Date: | 27-03-2023 |
| Application type: | Amendment |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |
| Approved WMO Date: | 24-07-2023 |
| Application type: | Amendment |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |
| Approved WMO Date: | 01-08-2023 |
| Application type: | Amendment |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |
| Approved WMO Date: | 30-10-2023 |
| Application type: | Amendment |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |
| Approved WMO Date: | 31-10-2023 |

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|---|---|
| Application type: | Amendment |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |
| Approved WMO Date: | 31-10-2023 |
| Application type: | First submission |
| Review commission: | METC Z: Zuyderland-Zuyd (Heerlen) |

# 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 |
|---|---|
| EU-CTR | CTIS2024-516645-39-01 |
| EudraCT | EUCTR2021-002145-15-NL |
| CCMO | NL77771.096.21 |