A study on the effect of information on the use of analgesics in patients after weight loss surgery.

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Although U.S. guidelines indicate that the use of NSAIDS should be avoided in patients after bariatric surgery, a significant portion of the population of patients who underwent bariatric surgery in Medical Center Leeuwarden (MCL) in the period...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25083

Bron
NTR

Verkorte titel
NUBS

Aandoening

bariatric surgery; use of NSAIDS
bariatrische chirurgie; gebruik van NSAID's

Ondersteuning

Primaire sponsor: Medisch Centrum Leeuwarden (MCL), Leeuwarden, The Netherlands
Medisch Centrum Leeuwarden (MCL), H. Dunantweg 2, 8934 AD Leeuwarden
Overige ondersteuning: Wetenschapsfonds MCL, Leeuwarden, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The percentage of users of NSAIDS in the period 6 months before the intervention and in the period 3 to 9 months after the intervention in comparison with the control group. The use is determined by collecting dispensing data from pharmacies 6 months before the intervention and 9 months after the intervention. The use of NSAIDS is to be considered as stopped if there is no use of an NSAID any more in the period 3 to 9 months after the intervention.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Although U.S. guidelines indicate that the use of NSAIDS should be avoided in patients after bariatric surgery, a significant portion of the population of patients who underwent bariatric surgery in Medical Center Leeuwarden (MCL) in the period October 2008 to December 2011, use an NSAID at some time after the bariatric surgery. Moreover in the MCL only half of the patients use a PPI while using an NSAID after bariatric surgery.
These data indicate that there is room for improvement in the prescribing and use of NSAIDs in patients who have undergone bariatric surgery.

Objective of the study:

Primary objective:

To determine the effect of an intervention on the level of reduction of the number of users of NSAIDS in patients who underwent bariatric surgery in Medisch Centrum Leeuwarden (MCL).

Secondary objectives:

To determine the effect of an intervention on the level of reduction of the use of NSAIDS in patients who underwent bariatric surgery in MCL. To study the use of proton pump inhibitors (PPIS) in patients who use an NSAID after bariatric surgery.

Study design:

A randomized controlled intervention study in patients who underwent bariatric surgery in

MCL between March 2011 and November 2011. There will be a nine months follow-up period after intervention.

Study population:

Patients who underwent bariatric surgery in MCL between March 2011 and November 2011.

Intervention:

The intervention is performed by sending a letter to patients and their family doctors belonging to the intervention group, with information about the risks of use of NSAIDS by patients after bariatric surgery. As a control, a group of patients is included in which no intervention is performed.

Primary study parameters/outcome of the study:

The percentage of users of NSAIDS in the period 6 months before the intervention and in the period 3 to 9 months after the intervention in comparison with the control group. The use is determined by collecting dispensing data from pharmacies 6 months before the intervention and 9 months after the intervention. The use of NSAIDS is to be considered as stopped if there is no use of an NSAID any more in the period 3 to 9 months after the intervention.

Secundary study parameters/outcome of the study:

The number of Defined Daily Doses (DDDS) of an NSAID in the period 6 months before the intervention and in the period 3 to 9 months after the intervention in comparison to the control group. The number of DDDS is determined by means of the amount of NSAIDS dispensed in the period 6 months before and 3 to 9 months after the intervention. The intervention is to be considered effective, if the mean number of DDDS of an NSAID in the period 3 to 9 months after the intervention is reduced by half in comparison with the mean number of DDDS of an NSAID in the period 6 months before the intervention.

The number of users of NSAIDS with no concurrent use of a PPI in the period 6 months before the intervention and in the period 3 to 9 months after the intervention in comparison to the control group.
There is concurrent use of a PPI with an NSAID if the period of use of a PPI has a ≥ 2/3 overlap with the period of use of an NSAID. The use is determined by collecting dispensing data from pharmacies 6 months before and 9 months after the intervention.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Safety issues are not applicable for this study. The current policy of the MCL is that prior to surgery bariatric surgeons inform patients that NSAIDs after bariatric surgery should be avoided whenever possible. Patients in the control group only undergo a randomization and then the regular procedure. For those patients this is only an observational study. Patients in the intervention group will get more information about the risks associated with the use of NSAIDs after bariatric surgery. The subsequent part of the study in patients in the intervention group, is also only observational. The burden and risks for patients participating in this study, in the intervention group, as well as the control group are very low. Two times during the study dispensing data are requested from pharmacies and nine months after the intervention all patients will get a telephone call in which a questionnaire is used to record OTC use of NSAIDS and indications for NSAID use.

Doel van het onderzoek

Although U.S. guidelines indicate that the use of NSAIDS should be avoided in patients after bariatric surgery, a significant portion of the population of patients who underwent bariatric surgery in Medical Center Leeuwarden (MCL) in the period October 2008 to December 2011, use an NSAID at some time after the bariatric surgery. These data indicate that there is room for improvement in the prescribing and use of NSAIDs and PPIs in patients who have undergone bariatric surgery. Informing patients and their family doctors about the risks of use of NSAIDS after bariatric surgery should reduce the use of NSAIDS.

Primary objective of the study:

To determine the effect of an intervention on the level of reduction of the number of users of NSAIDS in patients who underwent bariatric surgery in Medisch Centrum Leeuwarden (MCL).

Secondary objectives:

To determine the effect of an intervention on the level of reduction of the use of NSAIDS in patients who underwent bariatric surgery in MCL.

To determine the use of protonpump inhibitors in patients who use NSAIDS after bariatric surgery.

The intervention is performed by sending a letter to patients and their family doctors belonging to the intervention group, with information about the risks of use of NSAIDS by patients after bariatric surgery. As a control, a group of patients is included in which no intervention is performed.

Onderzoeksopzet

1. Before intervention;

2. Intervention;

3. 9 months after intervention.

Onderzoeksproduct en/of interventie

The intervention is performed by sending a letter to patients and their family doctors belonging to the intervention group, with information about the risks of use of NSAIDS by patients after bariatric surgery.

As a control, a group of patients is included in which no intervention is performed.

Two times during the study dispensing data are requested from pharmacies and nine months after the intervention all patients will get a telephone call in which a questionnaire is used to record OTC use of NSAIDS and indications for NSAID use.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients who underwent bariatric surgery in Medisch Centrum Leeuwarden (MCL) in the period March to November 2011;

2. Patients who signed and turned in a written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with no medication record at any moment of the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2012
Aantal proefpersonen:	240
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-10-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3485
NTR-old	NTR3665
Ander register	: RTPO 877
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A