Pharmacy based dosing of darbepoetin in haemodialysis patients of the Sint Franciscus Gasthuis.

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Dosage advice given by a pharmacist increases the part of the haemodialysis population that has adequate hemoglobin values (Hb 6,8-7,4 mmol/l) compared to dosing by the nephrologist alone.

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

Samenvatting

ID

NL-OMON20569

Bron
Nationaal Trial Register

Aandoening

english: haemodialysis pharmacy haemoglobin dosing advice
dutch: hemodialyse, apotheek, hemoglobine, doseeradvies

Ondersteuning

Primaire sponsor: Sint Franciscus Gasthuis
Overige ondersteuning: Sint Franciscus Gasthuis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Which percentage of haemodialysis patients reaches haemoglobin values within the target range (6.8-7.4 mmol/l) with darbepoetin dosage defined by nephrologist alone compared with

dosage defined by pharmacist and nephrologist?

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Treatment of anaemia with haematopoetic growth factors in end stage renal disease does not always lead to adequate haemoglobin values. At this moment, approximately a quarter of the dialysis population has an adequate haemoglobin value, defined as within the target range of 6.8 to 7.4 mmol/l. Previous research has shown that haemoglobin values lower or higher than within the target range may have serious consequences for the health of haemodialysis patients. Lower values can lead to lower quality of life and may deteriorate cardiac disease. Higher haemoglobin values may lead to higher cardiovascular mortality as recent research has shown. Further, higher haemoglobin values may lead to an increased incidence of shunt thrombosis, although studies are not conclusive on this subject.

Objective of the study:

To investigate if a dosage advice for darbepoetin and iron generated by a pharmacist leads to an increase of haemodialysis patients whose haemoglobin values lie within the target range, compared to dosage of darbepoetin by the nephrologist alone.

Study design:

This study is a prospective, randomized controlled trial with partial retrospective analysis. Patients are randomized between two groups: treatment by nephrologist alone, or treatment by nephrologist and pharmacist. The first group is the control group and gets standard treatment, The second group is the experimental group. For this last group treatment advice for darbepoetin and iron is monthly generated by a pharmacist, based on laboratory values (haemoglobin, ferritin, transferrin saturation) and recent dosage of darbepoetin and iron.

Study population:

All haemodialysis patients treated with darbepoetin in our hospital.

Intervention:

In the intervention group, the pharmacist advizes the nephrologist regarding the dosage of darbepoetin and iron based on recent haemoglobin values and iron status, as well as previous dosages of darbepoetin and iron. In the control group, dosage of darbepoetin is solely determined by the nephrologist.

Primary study parameters/outcome of the study:

Which percentage of haemodialysis patients reaches haemoglobin values within the target range (6.8-7.4 mmol/l) with darbepoetin dosage defined by nephrologist alone compared with dosage defined by pharmacist and nephrologist?

Secundary study parameters/outcome of the study:

1. Which part of haemodialysis patients before and after intervention reaches haemoglobin values within the target range (6.8-7.4 mmol/l) with darbepoetin dosage defined by nephrologist alone compared with darbepoetin dosage defined by pharmacist and nephrologist?

2. Which percentage of the haemoglobin values per patient lies within the target range before and after intervention, for the group treated by nephrologist alone as well as for the group treated by nephrologist and phamacist together?

3. Which proportion of haemodialysis patients before and after intervention reaches haemoglobin values within the wider target range (6.8-8.1 mmol/l) with darbepoetin dosage defined by nephrologist alone and with darbepoetin dosage defined by nephrologist and pharmacist together?

4. Which percentage of the pharmacist's advices is not acted on by the nephrologist and why?

5. Which percentage of haemodialysis patients before and after intervention has an adequate iron status with treatment defined by nephrologist alone compared with treatment defined by nephrologist and pharmacist together?

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

The burden for patients is minimal. The only differences between the two groups are that in the group treated by nephrologist and pharmacist administration of iron may be more

frequent (three times a week vs. once a week or less) and that during monthly blood withdrawal an extra vial of blood is necessary to determine iron status (once monthly vs. once in three months). Both differences do not lead to extra burden, because these procedures are executed during regular haemodialysis moments. The risk for patients is nil. In all cases, the nephrologist is responsible for the treatment and has the possibility to diverge from the pharmacist's advice for clinical reasons. Benefits of participation with this study may be better regulated haemoglobin values.

Doel van het onderzoek

Dosage advice given by a pharmacist increases the part of the haemodialysis population that has adequate hemoglobin values (Hb 6,8-7,4 mmol/l) compared to dosing by the nephrologist alone.

Onderzoeksopzet

Each patient is followed for 13 months, and 6 months retrospectively.

Onderzoeksproduct en/of interventie

In the intervention group, the pharmacist advices the nephrologist regarding the dosage of darbepoetin and iron based on recent haemoglobin values and iron status, as well as previous dosages of darbepoetin and iron. In the control group, dosage of darbepoetin is solely determined by the nephrologist.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All haemodialysis patients treated with darbepoetin.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with less than three prospective haemoglobin values included in data analysis.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	07-06-2010
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-02-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33197
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3652
NTR-old	NTR3836
CCMO	NL27341.101.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33197

Resultaten

Samenvatting resultaten
N/A