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

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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON33197

Source
ToetsingOnline

Brief title
Pharmacy based dosing of darbepoetin in haemodialysis patients

Condition

- Renal disorders (excl nephropathies)

Synonym
anaemia, end stage renal disease

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: financiering door instelling waar het onderzoek wordt uitgevoerd

Intervention

Keyword: dosing advice, haemodialysis, haemoglobin, pharmacy

Outcome measures

Primary outcome

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?

Secondary outcome

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?

Study description

Background summary

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.

Study objective

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.

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.

Study burden and risks

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.

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

All haemodialysis patients treated with darbepoetin

Exclusion criteria

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

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	09-09-2009
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20569
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL27341.101.09
OMON	NL-OMON20569

Study results

Date completed:	17-04-2014
Actual enrolment:	200