

Het effect van de vitamine B12 toediengsvorm op het verloop van de hoeveelheid vitamine B12 in het bloed.

Gepubliceerd: 27-07-2011 Laatste bijgewerkt: 19-03-2025

Intranasal administration of cobalamin can be used as an alternative for the standard intramuscular injection of cobalamin in cobalamin deficient patients.

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

Samenvatting

ID

NL-OMON20477

Bron

Nationaal Trial Register

Verkorte titel

not applicable

Aandoening

Cobalamin deficiency
(cobalamine deficiëntie of vitamine B12 deficiëntie, ouderen)

Ondersteuning

Primaire sponsor: Stichting Apotheek der Haarlemse Ziekenhuizen (SAHZ)

Overige ondersteuning: Stichting Apotheek der Haarlemse Ziekenhuizen (SAHZ)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Approximately 10-15% of the population aged 65 years and older has cobalamin (Vitamin B12) deficiency. An even higher prevalence of 30-40% is reported for malnourished and sick elderly people. Cobalamin serves as a cofactor for several vital biochemical reactions. If deficient, people may suffer from anaemia, irreversible neurological damage resulting in cognitive impairment, and neuropsychiatric disorders. Cobalamin deficiency is due to malabsorption of food-bound cobalamin or insufficient dietary intake. Administration of cobalamin by way of intramuscular injection is the gold standard for cobalamin deficiency treatment. It, however, has several disadvantages. Injections are painful, injection related adverse reactions may occur, and health care professionals are usually needed to administer these injections. The latter increases the costs of the treatment considerably. A more convenient, safer and cost-effective treatment would, therefore, be advantageous to both patients and the health care system in general. Food-bound cobalamin is actively absorbed. In contrast, crystalline cyanocobalamin administered in capsules is absorbed by way of passive diffusion although at a relatively low efficiency. Approximately 1% of an oral dose of crystalline cyanocobalamin is absorbed. Oral administration of cyanocobalamin is, however, efficacious in normalising serum cobalamin levels. Oral treatment is not an option in patients that are unable to take oral medication or patients with severe diarrhoea or vomiting. Dysphagia is a common condition in the elderly population due to age related pathologic changes or due to cerebrovascular diseases affecting the swallowing mechanism. Intranasal administration of cobalamin seems a suitable alternative for both cobalamin injections and oral administration in elderly. The absorption of intranasal administered cobalamin was demonstrated in two studies. In these studies, intranasal administration of cobalamin has not been compared to intramuscular administered cobalamin. Insight in the pharmacokinetics of intranasal administered cobalamin in comparison with intramuscular injection is, however, required to determine the optimal dosage regimen. In addition, the absorption of intranasal administered cobalamin has been examined in healthy elderly volunteers and patients with ileal resections or Crohn's disease only, though cobalamin deficiency is more prevalent in the sick and/or malnourished elderly population. In order to determine a dosage regimen for intranasal administered cobalamin in elderly patients insight in the pharmacokinetics of intranasal administration compared to intramuscular administration of cobalamin has to be obtained. Because there are no published pharmacokinetic data of intramuscular cobalamin in elderly patients both routes of administration need to be investigated. In this study we investigate the effects of two routes of administration i.e. cobalamin administered intranasally and cobalamin administered by intramuscular injection on the pharmacokinetics as expressed in the standard parameters AUC48hours, Cmax, Tmax and T1/2 in elderly patients.

Doel van het onderzoek

Intranasal administration of cobalamin can be used as an alternative for the standard intramuscular injection of cobalamin in cobalamin deficient patients.

Onderzoeksopzet

Blood samples will be drawn at $t = 0, 15, 30, 45, 60, 120, 240, 480, 1440, 2880$ minutes.

Onderzoeksproduct en/of interventie

1. 5 subjects will receive 1 dose of 1000 mcg cobalamin administered by intramuscular injection;
2. 5 subjects will receive 1 dose of 1000 mcg cobalamin administered by intranasal spray.

Contactpersonen

Publiek

Boerhaavelaan 22
C.J. Kalisvaart
Haarlem 2035 RC
The Netherlands
+31 (0)23 5453045

Wetenschappelijk

Boerhaavelaan 22
C.J. Kalisvaart
Haarlem 2035 RC
The Netherlands
+31 (0)23 5453045

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Cobalamin deficiency i.e. cobalamin level less than 200 pmol/l;

2. 65 years of age or over;
3. Capable of understanding the study information;
4. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Concomitant use of nasally administered medication;
2. Chronic Rhinitis;
3. Running nose;
4. Clinical relevant infection;
5. Hemodynamic instability;
6. Short Nutritional Assessment Questionnaire (SNAQ) score of 3 or over;
7. Use of cobalamin containing dietary supplements;
8. Severe Renal impairment i.e. MDRD less than 20 ml/min;
9. Ethical or medical reasons upon discretion of the investigators.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	27-07-2011
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	27-07-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36589
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2862
NTR-old	NTR3005
CCMO	NL33450.029.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36589

Resultaten

Samenvatting resultaten

N/A