Bilirubin treatment in humans; a study on safety and dose finding.

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Multiple observational and animal studies suggest a therapeutic effect of bilirubin in various diseases. To verify this suggestion, intervention studies with experimental hyperbilirubinemia are needed. The current study explores the applicability of...

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

Samenvatting

ID

NL-OMON25884

Bron
NTR

Verkorte titel
BILI

Aandoening

bilirubin, bilirubine, hart- en vaatziekten, cardiovascular disease

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre
Overige ondersteuning: Dutch Diabetes Research Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Bilirubin concentrations attained after parenteral administration.

Toelichting onderzoek

Achtergrond van het onderzoek

Parenteral
administration of bilirubin has been applied frequently in the past. For now, bilirubin is not commercially available for human research. As several observational studies suggest a beneficial effect of bilirubin with respect to for example cardiovascular disease, we will reintroduce bilirubin for parenteral human use to explore these findings. The current study is performed to assess pharmacokinetic data on intra-arterial and intravenous administration in healthy individuals. Furthermore, side effects will be monitored.

Doel van het onderzoek

Multiple observational and animal studies suggest a therapeutic effect of bilirubin in various diseases. To verify this suggestion, intervention studies with experimental hyperbilirubinemia are needed. The current study explores the applicability of the parenteral use of bilirubin, both with regards to safety and pharmacokinetics.

Onderzoeksopzet

The first phase of the study includes the intra-arterial administration of bilirubin. Subjects will be examined subsequently with invariably at least one week in between. Plasma samples will be taken on a regular base to study both local and systemic rises of the bilirubin level. On the condition that no adverse effects are noted, subjects will be re-examined in a second phase in which larger doses of bilirubin will be administered intravenously. Again, subjects will be examined subsequently with invariably at least one week in between. Plasma samples will be taken on a regular base to study systemic rises of the bilirubin level.

Onderzoeksproduct en/of interventie

Increasing amounts of bilirubin will be administered both intra-arterially (first phase - low total dose) and intravenously (second phase - high total dose). Dose levels will remain far below those levels reported safe in literature.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

At least 18 and not older than 65 years of age.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Cocumented history of sensitivity or indiosyncrasy to medicinal products or excipients;

2. History of or current abuse of drugs, alcohol or solvents;

3. Use of any medication except for anti-conceptives;

4. Sexually active women in reproductive age group without appropriate anti-conceptive therapy;

5. Any (sign of) active disease;

6. History of liver disease;

7. Laboratory results exceeding twice the upper limit of normal range;

8. Total bilirubin level of 10 micromol/L or higher, suggesting the presence of the Gilbert syndrome.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	14-12-2010
Aantal proefpersonen:	6
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-03-2011
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	NL2678
NTR-old	NTR2807
Ander register	CMO Regio Arnhem - Nijmegen : 2009/170
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A