BB3 in Kidney Transplantation.

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BB3 will improve kidney function in the immediate post-transplant period in patients who have received a DCD kidney transplantation.

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

Samenvatting

ID

NL-OMON22050

Bron
NTR

Aandoening

End-stage renal disease
kidney transplantation

nierfalen
niertransplantatie

Ondersteuning

Primaire sponsor: Angion Biomedica Europe LimitedAngion Biomedica Corp.1050 Stewart AvenueGarden City, NY 11530
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary analysis to assess the activity of BB3 compared to placebo will be the mean difference in creatinine clearance over time using selective 24-hour urine collections from the transplanted kidney from the first infusion of study drug through day 7 post-transplant. If a

subject has more than one creatinine value assessed during the 24-hour urine collection, the mean of the values will be used for calculation of creatinine clearance.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Kidney transplantation from donors after cardiac death (DCD) is associated with a high risk for delayed graft function (DGF) due to ischemic acute kidney injury (AKI). BB3 is a small-molecule hepatocyte growth factor mimetic that has been shown to improve early graft function after kidney transplantation in rats and dogs.

Objective of the study:

To evaluate the safety and activity of BB3 compared to placebo in improving renal function in the immediate posttransplant period in patients who have received a DCD kidney transplantation.

Study design:

The primary intent is a paired-kidney design. This means that both recipients must participate in the study. In some cases, this isn't possible. For example: if both kidneys are allocated to our centre, it is possible that the first recipient gives consent and is included in the study. This recipient will be randomized to receive either BB3 or placebo, while the second recipient is not yet available for consent. If the second recipient doesn't want to participate, the first recipient, who already got the first infusion, would be excluded, according to the paired-kidney study design. Inclusion of an unpaired-kidney recipient will allow inclusion of these subjects into the analysis.

Study population:

Wait-listed dialysis patients who receive a DCD kidney transplantation and have a creatinine clearance <10 mL/min in the first 2 hours after kidney transplantation.

Intervention:

One group receives 4 intravenous infusions of 2 mg/kg BB3 at 6-9, 24±3, 48±3 and 72±3 hours following kidney
transplantation and the other group receives an equal volume of normal saline at the same time points.

Primary study parameters/outcome of the study:

The primary analysis to assess the activity of BB3 compared to placebo will be the mean difference in creatinine clearance over time using selective 24-hour urine collections from the transplanted kidney from the first infusion of study drug through day 7 posttransplant.

Secundary study parameters/outcome of the study:

1. Safety;

2. Pharmacokinetics;

3. Incidence of delayed graft function;

4. Mean urine output;

5. Number of acute rejections;

6. Hospitalstay.

Doel van het onderzoek

BB3 will improve kidney function in the immediate post-transplant period in patients who have received a DCD kidney transplantation.

Onderzoeksopzet

Administration of investigational drug:

6-9, 24±3, 48±3, and 72±3 hours following transplantation.

Onderzoeksproduct en/of interventie

BB3 or placebo administration after kidney transplantation. One group receives 4 intravenous infusions of 2 mg/kg BB3 at 6-9, 24±3, 48±3 and 72±3 hours following kidney

transplantation and the other group receives an equal volume of normal saline at the same time points.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Subjects must sign the informed consent document prior to performance of any study related procedure including the Screening procedure;

2. Males and females ≥ 18 years of age;

3. Had renal transplantation due to end stage disease requiring chronic dialysis;

4. Study drug can be administered within 6 to 9 hours after transplantation;

5. Received kidney from donor after cardiac death;

6. DCD kidney fulfils the clinical site's criteria for transplantation;

7. Creatinine clearance from the transplanted kidney over a 2-hour collection period is <10 mL/min;

8. The contra lateral kidney will be transplanted at Maastricht University Medical Centre and its recipient is eligible to enroll and gives consent to participate in this trial (paired-kidney design). However if the second recipient of pair withdraws consent or no longer meets eligibility criteria after the first recipient has been enrolled, the first recipient will remain in the study;

9. Dry weight ≤ 100 kg;

10. Women of child bearing potential have a negative serum pregnancy test prior to transplantation;

11. Women of child bearing potential (including perimenopausal women who have had a menstrual period within 1 year) must agree to use 2 forms of effective birth control regimen (at least one-barrier method) during the 28-day study period. Men must agree to use condoms during the study period; A condom with spermicide is considered a single barrier;

12. In the opinion of the Investigator, the subject is capable of understanding and complying with the protocol.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Mean arterial pressure <40 mmHg or cardiac index <1.8 L/min/m2;

2. Requires emergency dialysis for reasons other than high plasma creatinine levels, e.g. severe fluid overload or severe metabolic abnormalities;

3. Recipient of multiple organ transplantation or scheduled for multiple organ transplantation;

4. Recipient of kidney from a paediatric donor age 10 years or less;

5. Recipient age > 75 years;

6. Patients with ASA 4 or 5;

7. Patients with chronic obstructive pulmonary disease (COPD) GOLD IV;

8. Has measurable donor-specific antibody or positive cross-match requiring deviation from standard immunosuppressive therapy;

9. Currently participating in or has participated in an investigational drug or medical device study within 30 days or five half-lives, whichever is longer, prior to enrolment into this study;

10. Subjects who are currently taking or within 2 weeks prior to Screening have taken medications for Parkinson's disease;

11. Subjects who are currently taking or within 2 weeks prior to Screening have taken medications for depression;

12. Repeated demonstration of QTc interval >450 ms for males and >470 ms for females on peri-operative and Screening ECGs;

13. Concurrent sepsis or active bacterial infection;

14. Have an active malignancy or history of solid, metastatic or haematologic malignancy with the exception of basal or squamous cell carcinoma of the skin that has been removed;

15. Women of child bearing potential who is breast feeding;

16. History of positive HIV test;

17. History of rheumatoid arthritis;

18. History of proliferative retinopathy or laser surgery for retinopathy;

19. Subjects who have a penicillin allergy;

20. Subjects who require medications metabolized by CYP1A2 (see Chapter 5.2), or are receiving ciprofloxacin and fluvoxamine (Luvox®);

21. Subject is unwilling or unable to comply with the protocol or to cooperate fully with the Investigator or the site personnel;

22. Subject is not deemed medically stable for the study in the opinion of the Investigator or the subject;s primary nephrologist.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2010
Aantal proefpersonen:	36
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-10-2010
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	NL2291
NTR-old	NTR2561
Ander register	MEC MUMC : 10-1-027
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A