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

Samenvatting

Bron

NTR

Verkorte titel

RESCUE

Ondersteuning

Primaire sponsor : Wyeth

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To determine the recurrence rate of biopsy-confirmed cutaneous SCC with sirolimus (SRL)-based immunosuppression over a 2 year period of follow-up.

Toelichting onderzoek

Achtergrond van het onderzoek

This open-label, randomized, parallel-group, comparative, outpatient study will include stable renal transplant recipients, at least 1 year post-transplantation, from transplant centers in The Netherlands and the United Kingdom. Patients will be randomized per site with stratification for the number of biopsy-confirmed cutaneous SCC and recipient age.

Doel van het onderzoek

It is hypothesized that conversion to a regimen with sirolimus, an effective immunosuppressive drug with antiproliferative properties, could diminish the recurrence rate of cutaneous SCC. The potential usefulness of sirolimus in the prevention of (recurrent) skin carcinoma is suggested not only by in vitro and pre-clinical studies, but also by preliminary results from studies in renal transplant recipients.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Sirolimus treatment arm:

1. Conversion to sirolimus:

At the time of randomization the patient stops the purine antagonist (azathioprine or mycophenolate mofetil) or the calcineurin inhibitor (cyclosporine or tacrolimus) on day 0 and starts the same day with sirolimus (day 0: loading dose; day 1: maintenance dose). Between day 5-7 a sirolimus trough level is measured and the dose adjusted to maintain/reach the defined range. (see below);

2. Sirolimus will be given as a loading dose of 8 mg, followed by a maintenance dose of 4 mg. The dose of sirolimus will be adjusted to achieve and maintain a whole blood trough concentration in the range of 5-10 ng/ml.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Organ (kidney or liver) transplant recipient with ³1 biopsy-confirmed cutaneous SCC;

2. Age ³18 years and at least 12 months post-transplantation;

3. Stable graft function (estimated GFR ³20 ml/min) while on a maintenance regimen with a calcineurin inhibitor, azathioprine, mycophenolate mofetil or steroids for at least 12 weeks before randomization;

4. No acute rejection episode within 12 weeks prior to randomization;

5. All female patients at risk for pregnancy must have a negative serum pregnancy test before randomization. Female patients at risk for pregnancy must agree to use a medically acceptable method of contraception throughout the treatment period and for 12 weeks after discontinuation of study medication;

6. Total white blood cell count >3,000/mm3, platelet count >75,000/mm3;

7. Fasting triglycerides <3.95 mmol/l, cholesterol <7.8 mmol/l, with or without statins;

8. Signed, dated, and witnessed (institutional review board (IRB)- or independent ethics committee (IEC)-approved) informed consent before screening and before any tests are performed that are specific to the protocol.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Metastatic cutaneous SCC;

2. Other malignancies (except for other skin cancers), documented after transplantation;

3. Serum creatinine (for renal allograft recipient) or bilirubine level (for liver allograft recipient) at screening that has increased by >30% above the last value obtained at least 12 weeks earlier;

4. Evidence of systemic infection at the time of randomization;

5. Prior or current use of SRL or any of its derivatives;

6. Use of investigational agents £ 4 weeks before randomization, except for topical dermatological products as Aldara (imiquimod) or Efudix (5-fluoro-uracil);

7. Use of immunosuppressive agents (at the time of randomization) other than calcineurine inhibitor, azathioprine, mycophenolate mofetil or prednisone;

8. Current use of terfenadine, cisapride, astemizole, pimozide, or cimetidine; these drugs must be discontinued before randomization;

9. Positive past medical history for documented human immunodeficiency virus (HIV) infection.

Onderzoeksopzet

Opzet

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

Controle :	Geneesmiddel

Deelname

Nederland

Status :	Werving gestopt
(Verwachte) startdatum :	01-01-2004
Aantal proefpersonen :	180
Type :	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum :	13-09-2005
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	NL349
NTR-old	NTR388
Ander register	: N/A
ISRCTN	ISRCTN98226084

Resultaten

Samenvatting resultaten

N/A