

Recurrent cutaneous squamous cell carcinoma under Rapamune®

Submission date 19/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/12/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/05/2013	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J W de Fijter

Contact details
Leiden University Medical Centrw
Department of Nephrology
C3-P22, P.O. Box 9600
Leiden
Netherlands
2300 RC
+31 (0)71 526 2169
jwdefijter@lumc.nl

Additional identifiers

Protocol serial number
NTR388

Study information

Scientific Title

A randomised, prospective, open-label, multi-centre study comparing the efficacy and safety of conversion to sirolimus in stable renal or liver transplant recipients with a cutaneous squamous cell carcinoma

Acronym

RESCUE

Study objectives

It is hypothesised that conversion to a regimen with Rapamune® (sirolimus), an effective immunosuppressive drug with antiproliferative properties, could diminish the recurrence rate of cutaneous squamous cell carcinoma (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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Multicentre, randomised, double blind, active controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Squamous cell carcinoma (SCC)

Interventions

Sirolimus treatment arm: conversion to sirolimus:

1. At the time of randomisation the patient stops the purine antagonist (azathioprine or mycophenolate mofetil) or the calcineurin inhibitor (cyclosporine or tacrolimus) on day zero and starts the same day with sirolimus (day zero: loading dose; day one: maintenance dose). Between days five and seven 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.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sirolimus (Rapamune®)

Primary outcome(s)

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

Key secondary outcome(s)

1. Number of hyperkeratotic skin lesions, located on: the dorsum of the hands, the forearms, the head.

Secondary safety:

2. Incidence and severity of biopsy-confirmed acute rejection
3. Treatment failure, defined as the occurrence of acute rejection or premature withdrawal from study medication for any reason
4. Differences in renal function as estimated by the Cockcroft-Gault equation in both renal and liver transplant recipients
5. Patient and graft survival

Completion date

01/01/2007

Eligibility

Key inclusion criteria

1. Organ (kidney or liver) transplant recipient with biopsy-confirmed cutaneous SCC
2. Aged over 18 years and at least 12 months post-transplantation
3. Stable graft function (estimated glomerular filtration rate [GFR] more than 20 ml/min) while on a maintenance regimen with a calcineurin inhibitor, azathioprine, mycophenolate mofetil or steroids for at least 12 weeks before randomisation
4. No acute rejection episode within 12 weeks prior to randomisation
5. All female patients at risk for pregnancy must have a negative serum pregnancy test before randomisation. 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 more than 3000/mm³, platelet count more than 75,000/mm³
7. Fasting triglycerides less than 3.95mmol/l, cholesterol less than 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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Metastatic cutaneous SCC
2. Other malignancies (except for other skin cancers), documented after transplantation
3. Serum creatinine (for renal allograft recipient) or bilirubin level (for liver allograft recipient) at screening that has increased by more than 30% above the last value obtained at least 12 weeks earlier
4. Evidence of systemic infection at the time of randomisation
5. Prior or current use of SRL or any of its derivatives
6. Use of investigational agents for less than four weeks before randomisation, except for topical dermatological products as Aldara® (imiquimod) or Efudix® (5-fluoro-uracil)
7. Use of immunosuppressive agents (at the time of randomisation) other than calcineurin inhibitor, azathioprine, mycophenolate mofetil or prednisone
8. Current use of terfenadine, cisapride, astemizole, pimozone, or cimetidine; these drugs must be discontinued before randomisation
9. Positive past medical history for documented human immunodeficiency virus (HIV) infection

Date of first enrolment

01/01/2004

Date of final enrolment

01/01/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Centrw

Leiden

Netherlands

2300 RC

Sponsor information

Organisation

Wyeth Pharmaceuticals B.V. (The Netherlands)

ROR

<https://ror.org/02bzf1224>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2013		Yes	No