Near-infrared fluorescence imaging in kidney transplantations using ZW800-1 for perfusion assessment: a pilot study

Published: 03-07-2018
Last updated: 11-04-2024

To assess the feasibility of ZW800-1 in the intraoperative assessment of kidney and ureter perfusion during kidney transplantations (living donor nephrectomy and transplantation)

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON46729

Source
ToetsingOnline

Brief title
ZW800-1 in kidney transplantations

Condition

- Renal disorders (excl nephropathies)
- Renal and urinary tract therapeutic procedures

Synonym
Kidney and ureters

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NIH en KWF grants

Intervention

Keyword: Fluorescence, Kidney transplantation, Perfusion

Outcome measures

Primary outcome

Efficacy endpoint: Signal-to-background ratio, defined as fluorescence signal in the kidney and ureter compared to fluorescence signal of the surrounding tissue.

Secondary outcome

Safety and tolerability endpoint: The occurrence or absence of adverse events following administration of ZW800-1 in patients.

Pharmacokinetic endpoint: Analysis of blood and urine samples for serum biochemistry, hematology and pharmacokinetics.

Study description

Background summary

Donor shortage remains one of the major problems in the field of kidney transplantation. Different methods of increasing the organ donor pool have been proposed by the scientific community. One of these measures is pushing the criteria of donor acceptance; more Expanded Criteria Donors (ECD) organs are being used for transplantation. This has significantly decreased the time a patient waits for a transplant. However, ECD organs also carry a higher risk of early graft loss, and would benefit of reliable and real-time viability measurements of kidney perfusion during surgery. Such measures would greatly help surgeons in deciding whether an ECD kidney can safely be transplanted. This would possibly reduce the considerable risk of Delayed-Graft-Function and primary non-function of the graft, which is associated with an increased risk of death.1

ZW800-1 is a novel zwitterionic fluorophore and is currently being studied in CME P17.125 to investigate its feasibility in ureter visualisation in real-time during surgery. ZW800-1 can also be used to assess kidney and ureter perfusion,

as it is exclusively renally cleared. However, very limited data are available on the value of fluorescence imaging during transplantation surgery. Donor organs, during procurement of the donor organs, during machine perfusion and immediately after transplantation are perfectly suitable for implementing fluorescent imaging. With the use of fluorescent imaging, kidney perfusion can be assessed to determine whether renally cleared fluorophores, such as ZW800-1, offer a reliable tool for real-time decision making during kidney donation and transplantation.

A number of pilot experiments are needed to establish whether the methods of fluorescence imaging are reliable and reproducible during kidney transplantations. Pre-clinical pilot experiments on fluorescence imaging during machine perfusion are already ongoing in collaboration with the Department of Surgical Sciences at the University of Oxford. The current proposal focuses on establishing a reproducible model in clinical kidney transplantation.

Study objective

To assess the feasibility of ZW800-1 in the intraoperative assessment of kidney and ureter perfusion during kidney transplantations (living donor nephrectomy and transplantation)

Study design

The study is an open-label pilot study consisting of 10 kidney transplantation couples (living kidney donor and kidney recipient). Patients (living kidney donor and kidney recipient) will be dosed with 2.5 mg ZW800-1 during surgery.

Intervention

Administration of ZW800-1 during surgery.

Study burden and risks

The risks of participation for the patients in the trial include hypersensitivity reactions. These risks are deemed minimal. Nevertheless precautionary measures (supervised administration by qualified staff and availability of medical treatmentto treat hypersensitivity reactions) are in place and these effects are generally well manageable. The burden ofthe trial is minimal, the research will coincide with routine care and the proposed procedures are minimally invasive. This research could possibly provide a useful tool to enhance visualization of ureters and assess kidney perfusion during surgery.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Patients > 18 years old;
2) Patient couples scheduled for a living donor nephrectomy and kidney transplantation;
3) Patients should be capable and willing to give informed consent before study specific procedures;
4) No unacceptable known cardiovascular or pulmonary disease, renal or liver dysfunction;
5) The screening ECG and laboratory test results are within normal limits, or if any are outside of normal limits they are considered to be clinically insignificant;
6) Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial.

Exclusion criteria

1) History of a clinically significant allergy or anaphylaxis;
2) Patients who previously underwent a kidney transplantation;
3) Patients pregnant or breastfeeding, lack of effective contraception in male or female patients with reproductive potential;
4) Any condition that the investigator considers to be potentially jeopardizing the patients well-being or the study objectives.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2019
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ZW800-1
Generic name:	niet van toepassing

Ethics review

Approved WMO

Date:	03-07-2018

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	26-11-2018
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	06-05-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2018-000985-12-NL
CCMO	NL65325.058.18