Neo-adjuvant versus Adjuvant chemotherapy in Upper Tract Urothelial Carcinoma: A feasibility phase II randomized clinical trial (*URANUS*)

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This study has been transitioned to CTIS with ID 2024-514991-41-01 check the CTIS register for the current data. To assess the proportion of UTUC patients with adequate renal function and fit to receive either neo- or adjuvant cisplatin-based…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON48801

Source
ToetsingOnline

Brief title
URANUS

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Genitourinary tract disorders NEC

Synonym
cancer in urinary upper tract, urethelial carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: investigator-initiated onderzoek

Intervention

Keyword: Adjuvant Chemotherapy, Neoadjuvant Chemotherapy, Radical nephroureterectomy, Upper Tract Urothelial Carcinoma (UTUC)

Outcome measures

Primary outcome

Proportion of UTUC patients with adequate renal function that were able to

receive either neo- or adjuvant cisplatin-based chemotherapy treatment

Proportion of UTUC patients randomized to neo- or adjuvant chemotherapy that

were able to start and finalize three courses of planned chemotherapy

Actually delivered dose vesus planned dose of chemotherapy administered in

patients randomized to neo- or adjuvant chemotherapy.

Secondary outcome

1- and 2-year Disease Free Survival (DFS), Overall Survival (OS) and

Cancer-Specific Survival (CSS)

Safety and tolerability of neo-adjuvant versus adjuvant chemotherapy

Evaluate histopathology in each group and histological response in the

neo-adjuvant patient group

Study description

Background summary

There are no definitive treatment recommendations for patients diagnosed with UTUC and therefore there is variable clinical practice amongst centres and

countries.
Radical nephroureterectomy (RNU) is considered the gold standard treatment and patients with good renal function are often offered perioperative chemotherapy
URANUS explores feasibility and collection of real world data of UTUC treatment in European and other countries (i.e. Japan).

Study objective

This study has been transitioned to CTIS with ID 2024-514991-41-01 check the CTIS register for the current data.

To assess the proportion of UTUC patients with adequate renal function and fit to receive either neo- or adjuvant cisplatin-based chemotherapy treatment
To assess the proportion of UTUC patients randomized to neo- or adjuvant chemotherapy that is actually able to start and finalize three courses of planned chemotherapy
To assess the administered versus planned dose of chemotherapy in patients randomized to neo- or adjuvant chemotherapy

Study design

URANUS Study is Cohort Prospective Exploratory phase II randomized clinical trial.
Patients with a diagnosis of invasive UTUC who are scheduled to undergo a radical nephro-ureterectomy (RNU) or distal ureterectomy and resection of all macroscopically abnormal nodes and clinically staged as cT2-cT4, cN0-N1 M0, will be included in the study. From this initial number of patients, a renal function evaluation will be performed.
Those who fulfil randomization treatment criteria (GFR >=55ml/min) and are able to receive chemotherapy will be randomized to adjuvant chemotherapy (after RNU)(GROUP C) or neo-adjuvant chemotherapy (before RNU)(GROUP B).
Patients allocated to neo-adjuvant or adjuvant chemotherapy will receive 3 cycles of gemcitabine/cisplatin or 3 cycles of dose dense methotrexate, vinblastine, doxorubicin, and cisplatin combination therapy. Patients with poor renal function (GFR<55ml/min) or with good renal function but unfit for cisplatin-based chemotherapy will not receive chemotherapy treatment (GROUP A).
Participants in the three groups will be followed up according to recommended routine practice. The study drugs are prescribed in routine clinical practice (clinical guidelines recommendation) in these patients. This study does not attempt to change chemotherapy prescribing habits.

Intervention

Surgery is standard patient care
Chemotherapy in patients with bladder and upper tract rinary carcinoma is often also considered standard of patient care.

Thus, no true intervention within the context of the study, while the study mainly aims to collect real world data

Study burden and risks

There is no extra burden or risk for patients in URANUS trial. The study is based on standard of care of UTUC patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Histological and radiological defined UTUC: Histologically-confirmed diagnosis of predominantly urothelial carcinoma of the upper urinary tract

Patients with UTUC cT2-cT4 cN0-N1 M0 (TNM classification)
Patients without bladder cancer or with concomitant non muscle invasive bladder cancer.
Adequate organ system function
CT scan of the chest, abdomen and pelvis and bone scan without evidence of distant metastasis

Exclusion criteria

Histology of pure adenocarcinoma, pure squamous cell carcinoma, sarcomatoid or predominant small cell carcinoma.
Any major contraindication to a surgical procedure.
Other active neoplasms.
Concomitant muscle invasive bladder cancer.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-05-2018
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ADRIAMYCIN

Generic name:	ADRIAMYCIN
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	CISPLATIN
Generic name:	CISPLATIN
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	GEMCITABINE
Generic name:	GEMCITABINE
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	METHOTREXATE
Generic name:	METHOTREXATE
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	VINBLASTIN
Generic name:	VINBLASTIN
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	06-07-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	27-11-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	31-10-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-04-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-03-2020
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
EU-CTR	CTIS2024-514991-41-01
EudraCT	EUCTR2016-004017-27-NL
ClinicalTrials.gov	NCT02969083
CCMO	NL60960.058.17