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Evaluating the biological effects of pre-operative intravenous administration of JX-594 (thymidine kinase-deactivated Vaccinia virus plus GM-CSF) prior to planned surgical resection of locally advanced/poor prognosis or metastatic cancers.

Submission date	Recruitment status	[_] Prospectively registered
26/08/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/08/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/05/2021	Cancer	

Plain English summary of protocol

Background and study aims
This is a clinical study to evaluate the biological effects of pre-operative intravenous administration of JX-594 (thymidine kinase-deactivated vaccinia virus plus GM-CSF) prior to planned surgical resection of locally advanced/poor prognosis or metastatic cancers.

Who can participate?
Adults aged 18 and older who have due to have surgery for metastatic cancer.

What does the study involve?
Pre-operative intravenous administration of JX-594.

What are the possible benefits and risks of participating?
Not provided at the time of registration.

Where is the study run from?
St. James's University Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2015 to July 2019

Who is funding the study?
Transgene (UK)

Who is the main contact?
Mrs Jenny Boards

Contact information

Type(s)
Scientific

Contact name
Mrs Jenny Boards

Contact details
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Additional identifiers

EudraCT/CTIS number
2012-000704-15

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19097

Study information

Scientific Title
A clinical study to evaluate the biological effects of pre-operative intravenous administration of JX-594 (thymidine kinase-deactivated Vaccinia virus plus GM-CSF) prior to planned surgical resection of locally advanced/poor prognosis or metastatic cancers.

Study objectives
A clinical study to evaluate the biological effects of pre-operative intravenous administration of JX-594 (thymidine kinase-deactivated vaccinia virus plus GM-CSF) prior to planned surgical resection of locally advanced/poor prognosis or metastatic cancers.

Ethics approval required
Old ethics approval format

Ethics approval(s)

GTAC190; First MREC approval date 31/08/2012

Study design
Non-randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Locally advanced/poor prognosis or metastatic cancer

Interventions
Pre-operative intravenous administration of JX-594

Intervention Type
Other

Primary outcome measure
To assess tissue and blood presence of JX-594

Secondary outcome measures
N/A

Overall study start date
10/08/2015

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. Patients with histologically proven or radiological findings consistent with locally advanced /poor prognosis or metastatic cancer, planned for surgical resection (curative or palliative) of primary or metastatic disease as part of standard clinical care. Patients with the following diseases will be eligible:
1.1. Metastatic melanoma due for lymph node dissection for lymph node macrometastases

(Stage IIIB/C) or
metastasectomy at any other site
1.2. Muscle-invasive transitional cell bladder cancer due for partial or total cystectomy
1.3. Primary hepatocellular carcinoma due for liver resection
1.4. Locally advanced/metastatic renal cell cancer planned for palliative nephrectomy
2. Willing to have full pre-operative workup prior to planned resection consistent with standard clinical practice appropriate for disease site and intervention planned
3. Fit for the planned surgical intervention
4. Life expectancy of at least 3 months
5. At least 18 years of age
6. Karnofsky Performance Score (KPS) = 70
7. Haemoglobin = 9 g/dL (correction with transfusion allowed)
8. Platelets = 100 x 109 (without platelet transfusion)
9. Absolute neutrophil count (ANC) = 1.5 x 109
10. Total bilirubin = 1.5 upper limit of normal (ULN)
11. AST or ALT = 2.5 ULN
12. INR = 1.7
13. Serum creatinine = 1.5 x ULN
14. For patients who are sexually active, able and willing to abstain from sex for 3 weeks following treatment. Willing to use barrier method to protect partner against infection for up to 6 weeks after the JX-594 treatment
15. Negative pregnancy test within 7 days of treatment if female and pre-menopausal
16. Willing and able to provide informed consent
17. Willing and able to comply with scheduled visits, the treatment plan and laboratory tests

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
1. Pregnant or nursing an infant
2. Patients on immunotherapy or known HIV infection or hepatitis B or C
3. Clinically significant active infection or uncontrolled medical condition (e.g. pulmonary, neurological, cardiovascular, gastrointestinal, genitourinary), such that unfit for surgery or interfering with interpretation of trial
4. Severe or unstable cardiac disease, including significant coronary artery disease requiring angioplasty or stenting within the preceding 12 months, unless well-controlled on stable medical therapy for at least 3 months
5. Known CNS malignancy (history of brain metastases completely resected or treated by gamma knife therapy or whole brain radiotherapy)

6. Clinically significant and re-accumulating ascites, pericardial and/or pleural effusions
7. Tumour(s) in a location that would potentially result in significant clinical adverse effects if post-treatment tumour swelling were to occur (e.g. tumours causing near total blockage of the common bile duct)
8. Anti-cancer therapy (e.g. chemotherapy, surgery, radiotherapy, investigational agent) within 4 weeks prior to treatment with JX-594
9. History of a severe systemic reaction or side-effect as a result of a previous smallpox vaccination
10. History of exfoliative skin condition (e.g. eczema or ectopic dermatitis) requiring systemic therapy

Date of first enrolment
10/08/2015

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St. James's University Hospital
Clinical Sciences Building
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Sponsor information

Organisation
University of Leeds

Sponsor details
Woodhouse Lane
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Sponsor type

University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Industry

Funder Name
Transgene

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Abstract results		01/10/2019	26/05/2021	No	No