

# 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.

<b>Submission date</b> 26/08/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/08/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/05/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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**  
St. James's University Hospital  
Clinical Sciences Building  
Level 6  
Beckett Street  
Leeds  
United Kingdom  
LS9 7TF

## 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 =  $100 \times 10^9$  (without platelet transfusion)

9. Absolute neutrophil count (ANC) =  $1.5 \times 10^9$

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

Level 6

Beckett Street

Leeds, West Yorkshire

United Kingdom

LS9 7TF

## Sponsor information

**Organisation**

University of Leeds

**Sponsor details**

Woodhouse Lane

Leeds

England

United Kingdom

LS2 9JT

**Sponsor type**

University/education

ROR

<https://ror.org/024mrx33>

## 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?
<a href="#">Abstract results</a>		01/10/2019	26/05/2021	No	No