

# VXM01 phase I dose escalation study in patients with locally advanced, inoperable and stage IV pancreatic cancer

<b>Submission date</b> 05/12/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/01/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/01/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The aim of the study is to test the safety and tolerability of VXM01, a novel anti-angiogenic cancer vaccine which targets the blood vessels of solid tumors. Signs of immunological and clinical response will also be monitored. This study is the first human clinical trial with VXM01. A mouse-analog vaccine has shown promising activity and a good safety profile in test animals. VXM01 is administered in ascending doses following a step-wise approach.

### Who can participate?

Locally advanced, inoperable and metastatic pancreatic cancer patients of aged 18 or over.

### What does the study involve?

All patients receive standard-of-care chemotherapy and are randomly allocated to receive either VXM01 or placebo (dummy).

### What are the possible benefits and risks of participating?

Not provided.

### Where is the study run from?

University Hospital in Heidelberg, Germany.

### When is study starting and how long is it expected to run for?

The study starts in December 2011, and patients will be followed up for a maximum period of 24 months.

### Who is funding the study?

VAXIMM GmbH, Mannheim, Germany.

### Who is the main contact?

Dr Thomas Schmidt

# Contact information

## Type(s)

Scientific

## Contact name

Dr Thomas Schmidt

## Contact details

Clinic of General Surgery  
Im Neuenheimer Feld 105  
University Clinics of Heidelberg  
Heidelberg  
Germany  
69120

# Additional identifiers

## ClinicalTrials.gov (NCT)

NCT01486329

## Protocol serial number

VXM01-01-DE

# Study information

## Scientific Title

VXM01 phase I dose escalation study in patients with locally advanced, inoperable and stage IV pancreatic cancer to examine safety, tolerability, and immune response to the investigational VEGFR-2 DNA vaccine VXM01: First-in-human, monocenter, double-blind, placebo-controlled, phase I dose escalation study

## Acronym

VXM01-01-DE

## Study objectives

The aim of the study is to test the safety and tolerability of VXM01, a novel anti-angiogenic cancer vaccine which targets the blood vessels of solid tumors. Signs of immunological and clinical response will also be monitored. This study is the first human clinical trial with VXM01. A mouse-analog vaccine has shown promising activity and a good safety profile in test animals. This study is conducted in a single center at the University Hospital in Heidelberg, Germany.

On 05/02/2014 the following changes were made to the trial record:

1. The anticipated end date was changed from 31/03/2013 to 01/12/2014
2. The target number of participants was changed from 37 to 72

## Ethics approval required

Old ethics approval format

## **Ethics approval(s)**

Ethics committee of the Medical faculty of Heidelberg, 15/11/2011, ref: AFmu-283/2011

## **Study design**

Monocenter double-blind placebo-controlled phase I dose escalation study

## **Primary study design**

Interventional

## **Study type(s)**

Screening

## **Health condition(s) or problem(s) studied**

Locally advanced, inoperable and stage IV pancreatic cancer

## **Interventions**

1. VXM01, live anti-angiogenic cancer vaccine, escalating doses
2. Placebo drink solution

## **Intervention Type**

Other

## **Phase**

Phase I

## **Primary outcome(s)**

Safety and tolerability: number of dose-limiting toxicities and maximum tolerated dose at day 38

## **Key secondary outcome(s)**

1. Immune response: number of positive patients
2. Clinical response: tumor staging according to Response Evaluation Criteria In Solid Tumors (RECIST) criteria
3. Tumor perfusion: tumor perfusion determined by dynamic contrast enhanced-magnetic resonance imaging (DCE-MRI)  
Measured upto 24 months

## **Completion date**

01/12/2014

## **Eligibility**

### **Key inclusion criteria**

1. Written informed consent, signed and dated
2. Locally advanced, inoperable and stage IV pancreatic cancer patients according to Union for International Cancer Control (UICC) based on diagnostic imaging using computer-tomography (CT) or histological examinations
3. Male or post-menopausal female
4. Age more than or equal to 18 years
5. Chemotherapy naive within 60 days before screening visit except gemcitabine treatment
6. Karnovsky index >70

7. Life expectancy > 3 months
8. Adequate renal, hepatic, and bone marrow function
9. Absolute neutrophil count >1500/ $\mu$ L
10. Hemoglobin >10 g/dL
11. Platelets >75000/ $\mu$ L
12. Prothrombin time and international normalized ratio (INR) <1.5 times upper limit of normal (ULN) (except under anticoagulant treatment)
13. Aspartate aminotransferase <4 times ULN
14. Alanine aminotransferase <4 times ULN
15. Total bilirubin <3 times ULN
16. Creatinine clearance estimated according to Cockcroft-Gault >30 mL/min
17. Proteinuria <1 g protein on 24 h urine collection

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. State after pancreas resection (complete or partial)
2. Resectable disease
3. Drug trial participation within 60 days before screening visit
4. Other previous or current malignancy except basal or squamous cell skin cancer, in situ cervical cancer, or any other cancer from which the patient has been disease-free for <2 years
5. Prior vaccination with Ty21a
6. Cardiovascular disease defined as:
  - 6.1. Uncontrolled hypertension (systolic blood pressure >160 mmHg or diastolic blood pressure >100 mmHg)
  - 6.2. Arterial thromboembolic event within 6 months before randomization including:
    - 6.2.1. Myocardial infarction
    - 6.2.2. Unstable angina pectoris
    - 6.2.3. Cerebrovascular accident
    - 6.2.4. Transient ischemic attack
  7. Congestive heart failure New York Heart Association grade III to IV
  8. Serious ventricular arrhythmia requiring medication
  9. Clinically significant peripheral artery disease > grade 2b according to Fontaine
  10. Hemoptysis within 6 months before randomization
  11. Esophageal varices
  12. Upper or lower gastrointestinal bleeding within 6 months before randomization
  13. Significant traumatic injury within 4 weeks before randomization
  14. Non-healing wound, bone fracture or any history of gastrointestinal ulcers within three years

before inclusion, or positive gastroscopy within 3 months before inclusion

15. Gastrointestinal fistula

16. Thrombolysis therapy within 4 weeks before randomization

17. Bowel obstruction within the last 30 days before screening visit

18. Liver cirrhosis  $\geq$  grade B according to Child-Pugh Score-Classification

19. Presence of any acute or chronic systemic infection

20. Radiotherapy within 4 weeks before randomization

21. Major surgical procedures, or open biopsy within 4 weeks before randomization

22. Fine needle aspiration within 7 days before randomization

23. Chronic concurrent therapy within 2 weeks before and during the double-blind study period with:

23.1. Corticosteroids (except steroids for adrenal failure) or immunosuppressive agents

23.2. Antibiotics

23.3. Bevacizumab

23.4. Any epidermal growth factor receptor inhibitor

23.5. Chemotherapy except gemcitabine before day 10

24. Multi-drug resistant gram-negative germ

25. Pregnancy

26. Lactation

27. Inability to comply with study and/or follow-up procedures

28. History of other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of an investigational drug or that might affect the interpretation of the study results or render the patient at high risk for treatment complications

29. Women of childbearing potential

30. Any history of drug hypersensitivity

31. Any condition which results in an undue risk for the patient during the study participation according to the investigator

#### **Date of first enrolment**

06/12/2011

#### **Date of final enrolment**

01/12/2014

## **Locations**

#### **Countries of recruitment**

Germany

#### **Study participating centre**

**Clinic of General Surgery**

Heidelberg

Germany

69120

## **Sponsor information**

## Organisation

VAXIMM GmbH (Germany)

## ROR

<https://ror.org/03x5tah73>

## Funder(s)

### Funder type

Industry

### Funder Name

VAXIMM GmbH (Germany)

## 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?
<a href="#">Results article</a>	results	16/03/2015	21/01/2019	Yes	No
<a href="#">Results article</a>	results	16/01/2018	21/01/2019	Yes	No
<a href="#">Protocol article</a>	protocol	20/08/2012		Yes	No