ISRCTN16857581 https://doi.org/10.1186/ISRCTN16857581

An open, randomised phase I/II dose escalation study evaluating the safety and tolerability, pharmacokinetics, antigenicity and efficacy of Iodine-131-Kab201 when given intra-arterially or intravenously in patients with surgically unresectable pancreatic ductal adenocarcinoma

Submission date 12/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/10/2005	**Overall study status** Completed	
Last Edited 10/05/2012	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/monoclonal-antibody-and-iodine-treatment-for-advanced-cancer-of-the-pancreas

Study website
http://www.liverpool.ac.uk/surgery/ATrial.html

Contact information

Type(s)
Scientific

Contact name
Prof John Neoptolemos

Contact details
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP
+44 (0)151 706 4175
j.p.neoptolemos@liverpool.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
KSB303PAN/C1/001

Study information

Scientific Title

Acronym
KaBI

Study objectives
To assess the safety, tolerability and efficacy of targeted radiotherapy to pancreas using anti-carcinoembryonic antigen (CEA) monoclonal antibody labelled with Iodine-131.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Pancreatic adenocarcinoma unsuitable for curative resection.

Interventions
Iodine-131-Kab201 given intra-arterially or intravenously

Intervention Type
Other

Phase
Phase I/II

Primary outcome measure
To evaluate the safety, tolerability and maximum tolerated dose of Iodine-131-Kab201 when administered either intra-arterially or intravenously in patients with unresectable pancreatic cancer.

Secondary outcome measures
To assess the pharmacokinetics, antigenicity and evaluate efficacy of Iodine-131-Kab201 when administered either intra-arterially or intravenously in patients with unresectable pancreatic cancer.

Overall study start date
01/09/2002

Completion date
31/10/2005

Eligibility

Key inclusion criteria
1. Male or female; aged 18 or over
2. Histologically proven diagnosis of ductal adenocarcinoma in the head of the pancreas
3. Advanced pancreatic ductal adenocarcinoma involving the head of the pancreas and thus unsuitable for potentially curative resection
4. At least one confirmed and measurable tumour site on computed tomography (CT) documented within 4 weeks of randomisation
5. Karnofsky Score of 70 or more
6. Life expectancy of greater than or equal to 3 months
7. Women of childbearing potential must have a negative pregnancy test at the time of screening and must be willing to practice appropriate contraceptive methods for the duration of the study. Men with partners of childbearing potential must also be willing to practice appropriate barrier contraceptive methods for the duration of the study.
8. Written informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
6 to 48

Key exclusion criteria
1. Leucopenia and/or granulocytopenia
2. Thrombocytopenia
3. Significant and worsening hepatic impairment (aspartate aminotransferase/alanine aminotransferase [AST/ALT] >3 x the upper limit of normal [ULN]; bilirubin >5 x ULN) in the absence of obstructive jaundice. Liver function tests must be stable or improving at time of investigational drug administration.
4. Significant renal impairment (serum creatinine >ULN)
5. Known immunological reactions to previously administered antibodies, proteins or iodine
6. Pregnant or lactating women
7. Radiotherapy or chemotherapy within the preceding 1 month at the scheduled time of dosimetric dosing (preceding 6 weeks for nitrosoureas)
8. Previous external beam radiotherapy to maximal tolerable levels to any critical organ (3000 cGy for liver, 2000 cGY for lungs/kidneys)
9. Treatment with any other clinical trial medication within the 3 months prior to dosimetric dosing
10. Presence of concomitant condition or circumstances which, in the opinion of the investigator, would render the patient unsuitable for the study, such as ongoing alcohol or drug abuse or being unable to tolerate any of the study procedures (e.g. unable to lie flat for nuclear imaging scans)

Date of first enrolment
01/09/2002

Date of final enrolment
31/10/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Liverpool University Hospital
Liverpool
United Kingdom
L7 8XP

Sponsor information

Organisation
Xenova Ltd (UK)

Sponsor details
957 Buckingham Avenue
Slough, Berkshire
United Kingdom
SL1 4NL

Sponsor type
Industry

Website
http://www.xenova.co.uk

Funder(s)

Funder type
Industry

Funder Name
Xenova Ltd

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?
Results article	results:	21/07/2006		Yes	No