

Mistletoe therapy for Advanced PAncreatic Cancer

Submission date 08/12/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/02/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 30/12/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
29/07

Study information

Scientific Title
Mistletoe therapy for advanced pancreatic cancer: a group sequential, randomised, phase III, open label study

Acronym
MAPAC

Study objectives

Primary hypothesis:

Patients receiving Iscador Qu Spzial (IQUS) will show a higher overall survival rate.

Secondary hypothesis:

Patients receiving IQUS will show improved (better) quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Clinical Centres of Serbia gave approval on the 4th March 2008 (ref: 60 /6)

Study design

Group sequential randomised open label phase III study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pancreatic cancer stage III and IV

Interventions

Subcutaneous (s.c.) injection of an extract of *Viscum album* (L.), the generic name of the investigational product is "Iscador Qu Spzial".

The dosage begins for all patients in the verum group with an initial phase: 2 x 0.01 mg, 2 x 0.1 mg, 5 x 1 mg, 5 x 5 mg, and 10 mg. For the following maintenance phase, the highest dosage of 10 mg is recommended. During the initial and the maintenance phase the dosage will be modified according to the patients tolerability. The investigational product is injected subcutaneously 3 times weekly. Patients in the mistletoe group will administer the investigational product for 12 months. All patients of the study are followed up 12 months after inclusion into the study.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Iscador Qu Spzial (IQUS)

Primary outcome(s)

Overall survival rate, followed up after inclusion at months 1, 2, 3, 6, 9, and 12.

Key secondary outcome(s)

Quality of life questionnaire, measured using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30), followed up after inclusion at months 1, 2, 3, 6, 9, and 12.

Completion date

31/12/2014

Eligibility

Key inclusion criteria

1. Patients with diagnosis of locally advanced or metastatic adenocarcinoma of the pancreas, and, if easily accessible, histo- or cytologically confirmed
2. Aged greater than or equal to 18 years at study enrolment, either sex
3. Written informed consent must be given voluntarily
4. Patients not eligible for gemcitabine
5. Leucocytes greater than 3000/mm³
6. Thrombocytes greater than 100,000/mm³
7. Serum creatinine less than 2 mg %
8. Serum glutamic oxaloacetic transaminase (SGOT) less than 3.5-fold upper institutional limit (liver metastasis: five-fold upper institutional limit)
9. Serum glutamic pyruvic transaminase (SGPT) less than 3.5-fold upper institutional limit (liver metastasis: five-fold upper institutional limit)
10. Adequate negative pregnancy test and adequate contraception (where appropriate)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

220

Key exclusion criteria

1. Pregnancy or breastfeeding
2. Terminally ill patients (life expectancy less than 4 weeks)
3. Significant weight loss (less than 20% body weight in the preceding 6 weeks)
4. Current use of immunostimulant or immuno-suppressive agents except therapeutics within the routinely administered standard therapy "best supportive care"
5. Current use of investigational agents or participation in a clinical study during the last 4 weeks
6. Clinically significant unrelated systemic illness

7. Co-morbidity with one of the following:

7.1. Diabetes mellitus

7.2. Active tuberculosis

7.3. Active thyroid hyperfunction

7.4. Cancer

7.5. Human immunodeficiency virus (HIV)-infection/acquired immune deficiency syndrome (AIDS)

7.6. Other severe systemic diseases as cardiac insufficiency, parasitosis or Crohn's disease

7.7. Acute inflammatory diseases with body temperature greater than 38°C

8. Drug abuse, alcohol abuse, methadone treatment

9. Known hypersensitivity to mistletoe-containing products

10. Second primary malignancy

11. Known brain metastasis

Date of first enrolment

01/01/2009

Date of final enrolment

31/12/2014

Locations

Countries of recruitment

Germany

Serbia

Study participating centre

Zechenweg 6

Freiburg

Germany

79111

Sponsor information

Organisation

Society for Cancer Research (Verein fuer Krebsforschung) (Switzerland)

ROR

<https://ror.org/045jyg234>

Funder(s)

Funder type

Research organisation

Funder Name

Society for Cancer Research (Verein fuer Krebsforschung) (Switzerland)

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?
Results article	results	21/07/2014	30/12/2020	Yes	No