# Mistletoe therapy for Advanced PAncreatic Cancer

Submission date 08/12/2008	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 05/02/2009	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 30/12/2020	<b>Condition category</b> Cancer	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

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

**Secondary identifying numbers** 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

Secondary study design Randomised controlled trial

Study setting(s) Hospital

**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 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 measure

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

#### Secondary outcome measures

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.

#### Overall study start date

01/01/2009

#### **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/mm^3
- 6. Thrombocytes greater than 100,000/mm^3
- 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

**Age group** Adult

Lower age limit

18 Years

**Sex** Both

Target number of participants 434

**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 therapeuticals 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)

**Sponsor details** Kirschweg 9 Arlesheim Switzerland 4144

**Sponsor type** Research organisation

Website http://www.hiscia.ch/

ROR https://ror.org/045jyg234

### Funder(s)

**Funder type** Research organisation

**Funder Name** Society for Cancer Research (Verein fuer Krebsforschung) (Switzerland)

### **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	21/07/2014	30/12/2020	Yes	No