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Mistletoe therapy for Advanced PAncreatic Cancer

Submission date	Recruitment status	[_] Prospectively registered
08/12/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2020	Cancer	

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