

Advanced Therapy Access Program (ATAP): a treatment for refractory cancer with oncolytic viruses

Submission date 08/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/05/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2022	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ATAP

Study information

Scientific Title

Open label oncolytic virus treatment of refractory cancer under the EU hospital exemption, article 28 of Regulation 1394/2007/EC

Acronym

ATAP

Study objectives

Oncolytic viruses as monotherapy and/or in combination with selected virus sensitizers or other cancer therapies are a safe treatment modality and may improve the quality of life and survival of patients with advanced cancer

As of 24/04/2012, anticipated end date of trial has been updated from 31/12/2019 to 31/03/2012.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Helsinki Central Hospital Surgical Ethics Committee decided that since ATAP is a virus treatment program under EU hospital exemption and in that regard not a formal clinical trial, Ethics committee's approval is not required.

Study design

Personalized virus therapy for individual cancer patients with refractory solid tumors

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

http://www.docrates.com/images/stories/pdf/Potilasinformaatio_ja_suostumuslomake_30_Aug_2010.pdf (Finnish) Not available in web format, please use the contact details below to request a patient information sheet (English)

Health condition(s) or problem(s) studied

Advanced solid tumors

Interventions

Personalized treatment with oncolytic viruses where the virus type, dose, dosing regimen, virus sensitizers, combination therapies and route of injection is optimized for each individual

Intervention Type

Other

Phase

Phase II/III

Primary outcome measure

1. Timepoints: Measured at baseline and at 3 months. However there is certain variability since each patient treatment is personalized and follow-up may be adjusted accordingly.
2. Methods:
 - 2.1. RECIST 1.1
 - 2.2. Modified PET Response Criteria in Solid Tumors
 - 2.3. Applicable tumor markers from serum, depending on cancer type
 - 2.4. Overall survival as days from first treatment

Secondary outcome measures

1. Safety
2. Adverse events
3. Overall Survival
4. Progression Free Survival
5. Imaging (PET, CT, MRI) based responses
6. Tumor marker responses
7. Symptomatic responses
8. Quality of life
9. Correlative biological data

Overall study start date

12/11/2007

Completion date

31/03/2012

Eligibility**Key inclusion criteria**

Solid tumor cancer progressing after available routine therapies

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Ongoing treatment program with no pre-defined limits. Patients recruited from Finland and other countries.

Key exclusion criteria

1. Known brain metastases
2. Recent thromboembolic event
3. Clinically significant active infection
4. Clinically significant medical condition considered high risk for experimental therapy (e.g. pulmonary, neurological, cardiovascular)
5. Severe or unstable cardiac disease
6. History of hepatic dysfunction
7. Cirrhosis or hepatitis
8. Women who are pregnant or nursing an infant
9. Previous organ transplant

Date of first enrolment

12/11/2007

Date of final enrolment

31/03/2012

Locations**Countries of recruitment**

Finland

Study participating centre

Cancer Gene Therapy Group

Helsinki

Finland

00290

Sponsor information**Organisation**

Oncos Therapeutics Ltd (Finland)

Sponsor details

Saukonpaadenranta 2

Helsinki

Finland

00180

Sponsor type

Research organisation

Website

<http://www.oncos.com>

ROR

<https://ror.org/00b8bzq64>

Funder(s)

Funder type

Research organisation

Funder Name

Oncos Therapeutics (Finland)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

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		01/02/2022	26/10/2022	Yes	No