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

Submission date 08/04/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/05/2011	**Overall study status** Completed	
Last Edited 26/10/2022	**Condition category** 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
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