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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Akseli Hemminki

Contact details
Cancer Gene Therapy Group
University of Helsinki
Haartmaninkatu 8
Biomedicum B506b
Helsinki
Finland
00290

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

Completion date
31/03/2012

Eligibility

Key inclusion criteria
Solid tumor cancer progressing after available routine therapies

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

ROR
https://ror.org/00b8bzq64

Funder(s)

Funder type
Research organisation

Funder Name
Oncos Therapeutics (Finland)

Results and Publications

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

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes