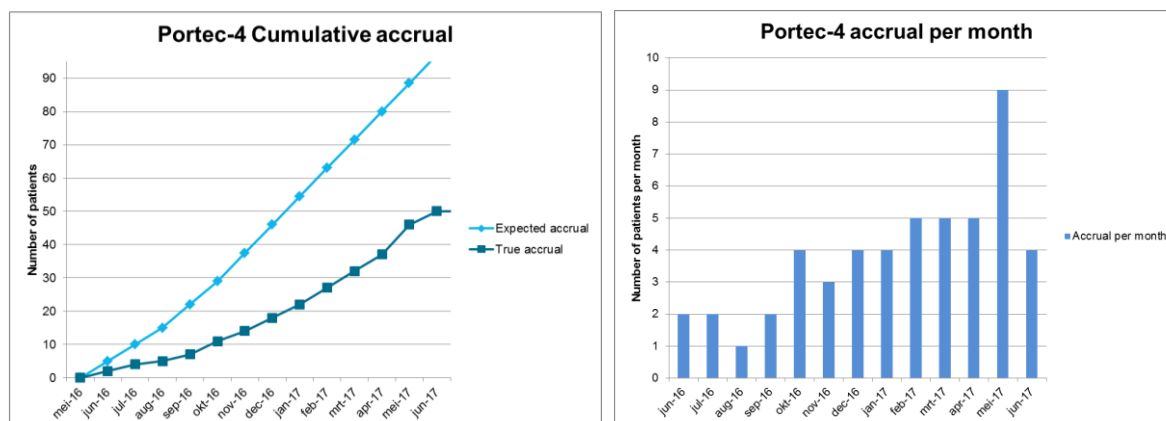


Pilot phase PORTEC-4a completed at 50 patients!

Accrual to the new design of the PORTEC-4 trial (PORTEC-4a) has reached the completion of the pilot phase (50th patient) on June 12th 2017.

In view of the poor patient acceptance of the previous design (with randomisation for vaginal brachytherapy or observation), one of the main aims of the pilot phase of the PORTEC-4a trial was to evaluate patient acceptance of the trial. It has turned out that in general, patients are positive about the individual risk assessment and determination if vaginal brachytherapy is recommended or if observation seems justified. In most of the current active sites, about 1 in 2 patients give informed consent to the trial.

See the graphs below showing the accrual over the past 12 months.



Evaluation of the pilot phase

Formal evaluation of the pilot phase (endpoints: patient acceptance and logistics of determination of the molecular profile within 2 weeks) will be done over the next months. A report will be sent to the Ethics Committee, the Data and Safety Monitoring Board and to the participating sites.

PORTEC-4a site initiations

One of the main reasons for the relatively slow accrual in the first few months after start of the new trial design in June 2016 is the more extensive local initiation

procedures in the participating centers. The table below shows the current active sites, the site approval dates and the accrual to date (51 patients on June 23rd). Some of the centers are still in the local approval phase, it is expected that most will be open to patient recruitment soon.

Center	Date kick off	Date local approval	Date first patient	No of patients
Academic Medical Center	02-06-16	Nov 2016	19-12-2016	5
Arnhem - Radiotherapy Goup	02-06-16	Sept 2016	26-09-2016	5
Catharina Hospital	28-06-16	Sept 2016	28-09-2016	4
Deventer - Radiotherapy Group	02-06-16	Sept 2016	-	0
Erasmus Medical Center	09-02-17	June 2017?	-	0
Haaglanden Medical Center	02-06-16	April 2017	03-04-2017	1
Isala Clinics	17-06-16	Sept 2016	07-11-2016	2
Leiden UMC	02-06-16	May 2016	10-06-2016	13
MAASTRO Clinic	02-06-16	Sept 2016	03-11-2016	13
Medical Spectre Twente	02-06-16	-	-	0
NKI/Antoni v. Leeuwenhoekhuis	02-06-16	April 2017	20-04-2017	2
Radiotherapy Inst Friesland	02-06-16	Sept 2016	18-10-2016	3
UMC Groningen	24-06-16	Sept 2016	-	0
UMC Radboud	30-06-16	-	-	0
UMC Utrecht	17-02-17	April 2017	-	0
Verbeeten Institute	30-06-16	Nov 2016	27-12-2016	3
Zuidwest RTI	28-03-17	March 2017	-	0
Total				51

DSMB

The Data and Safety Monitoring Board will have their first formal teleconference to evaluate the results of the pilot phase of the trial, and annually thereafter.

International participation to PORTEC-4a

The PORTEC-4a trial has attracted international attention at GCIG and IGCS meetings in Lisbon 2016, and as a result several groups are interested in participation. Two main groups which have very actively participated in PORTEC-3 – NCRI (UK) and ANZGOG (Australia and New Zealand) - have recently submitted grant applications to their national funding bodies and expect notice in November 2017.

Radiotherapy QA

After the dummyrun procedure for brachytherapy before participation in the PORTEC-4a trial, there will be a QA procedure of 1 brachytherapy treatment plan per participating center each year. The first QA round will be initiated over the coming months. Remi Nout has presented first results of the dummyrun procedure at ESTRO in May 2017. After the first QA round, a paper will be written to report on the combined dummyrun and QA results.

Data management, trial coordination and other news

Karen Verhoeven-Adema is the PORTEC-4a central datamanager and coordinator at the IKNL Trial Office, please email her at portec@iknl.nl or k.verhoeven@iknl.nl

- Please always use the most recent CRF version – see the PORTEC-4a website www.msbi.nl/portec4
- Summary cards (zakkaartjes) of the PORTEC-4a trial (inclusion criteria and logistics) are available and have been sent to the centres
- Bastiaan Wortman is our new PORTEC-PhD candidate; he will be starting as AIOS in Radiation Oncology as of August 1, 2017 and will combine his residency with his PhD project. He will be working on long-term results of the PORTEC-2 trial, and on the feasibility study and the dummyrun/QA of the PORTEC-4a trial.
- A trial article about PORTEC-4a has appeared in NTVO in March 2017; a copy can be requested