

Welcome!

To the first issue of the POLAR Express, a short news-flash for Principal Investigators, Data Managers, Trial Nurses, and Clinical Research Associates who actively work on the POLAR Trial.

We plan to issue the POLAR Express on a regular basis to give you study updates and inform you about recent developments and news. Stay tuned!

Of Special Interest

Current Accrual: 3
 Accrual Goal: 400
 No. of Centers Activated: 16
 *As of 12-Dec-2019

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Message from the Trial Chairs

Local or regional recurrence indicates a poor prognosis. A high proportion of patients with isolated locoregional recurrences (ILRR) of breast cancer are at substantial risk of developing distant metastasis. The results from IBCSG 27-02 CALOR Trial strongly suggested that tailoring treatment according to the disease characteristics of the local recurrence is superior to using characteristics of the primary tumor. Building on these results, the POLAR Trial will investigate whether adjuvant treatment with the CDK4/6 inhibitor palbociclib plus endocrine therapy prolongs disease-free survival compared to endocrine therapy alone for patients with ILRR of breast cancer.

The trial idea was developed back in 2017 and presented at the IBCSG Annual Meeting in March 2018. After the great effort to secure funding and develop the protocol, we are most happy to see that the trial has finally started.

We take this opportunity to welcome you all aboard the POLAR Trial and thank for your commitment.

Sincerely,
 Dr. Elisabetta Munzone, Trial Chair
 Dr. Stefan Aebi, Trial Co-Chair

POLAR Trial Schema

- ILRR of BC
- HR-positive and
- HER2-negative
- women or men

SURGERY

≤6 months

R

Arm A:
 Palbociclib for 3 years
 Standard ET (3+ years)

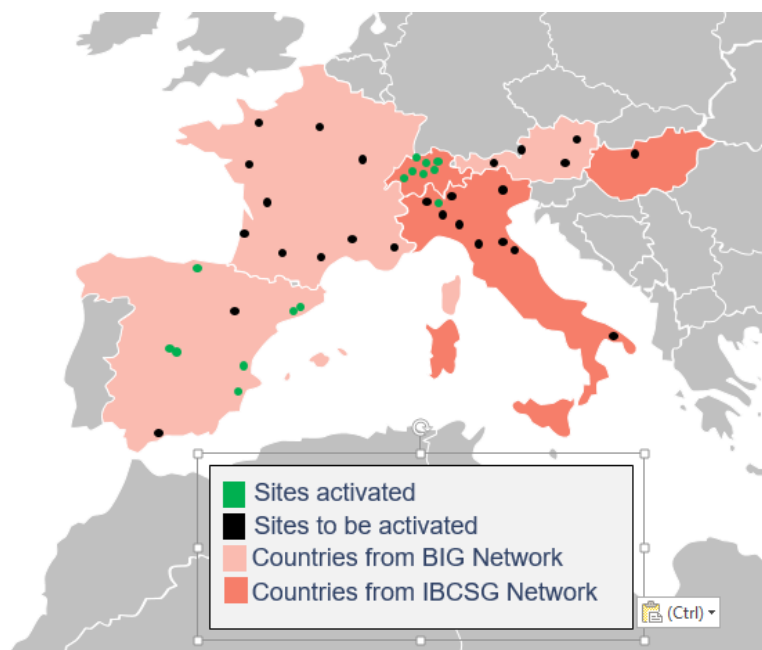
Arm B:
 Standard ET (3+ years)

1:1

Participating Countries

The POLAR Trial is sponsored and coordinated by IBCSG under the BIG umbrella. It is being conducted in three IBCSG countries: Hungary, Italy and Switzerland as well as in Austria (ABCSG), France (Unicancer) and Spain (GEICAM & SOLTI). Currently, we have Centers open in Switzerland, Italy and Spain, and are looking forward to the expansion of the POLAR Trial into our other partnering countries.

The first Center was activated on 27 August 2019 and as of 12-Dec-19, 16 Centers are open to recruit patients.



Accrual and Activation

Country	Number of Centers			Accrual
	Planned	Open	Recruiting	
Switzerland (IBCSG)	7	7	1	1
Spain (GEICAM & SOLTI)	10	8	2	2
Italy (IBCSG)	10	1	0	0
Hungary (IBCSG)	1	0	0	0
France (Unicancer)	10	0	0	0
Austria (ABCSG)	4	0	0	0
Total	42	16	2	3

POLAR currently has three patients enrolled. The first patient was randomized on 27 August 2019 at the Brustzentrum in Zürich, Switzerland. The second patient was randomized on 6 November 2019 at the Hospital de Basurto in Bilbao, Spain and the third patient on 12 December 2019 at the Institut Català d'Oncologia - ICO L'Hospitalet in Barcelona, Spain. We expect the accrual to pick up speed as more Centers are activated.

Thank you very much for your efforts to screen for patients.



DFexplore Tips

- Queries can be accessed and answered at any time.
- After opening a form, always navigate each field by using the Tab key so auto-population and warnings, if applicable, can pop up and prompt you to either enter or correct data.
- If an answer to a question is unknown, not done or unattainable, this can be noted using the Missing Value function. Do not leave the question blank. If at any time you wish to enter data in these fields, select "No Code (reset)" to change the field back to its original color and enter data.
- If you are experiencing any issues with DFexplore, please contact our User Support Team for assistance at datafax.user.support@fstrf.org

Trial Resources

- [IBCSG Website](#)
- [DFexplore User Manual](#)
- [POLAR Data Manager's Manual](#)
- [POLAR and DFexplore Training Slides](#)

The POLAR Team is always ready to answer your questions:
ibcsg59_polar@frontierscience.org

Latest News

Reporting SAEs after the End of Treatment Visit

A recently distributed letter to the Principal Investigators of the POLAR Trial highlights important information concerning the SAE reporting requirements after completion or discontinuation of protocol treatment that is missing in the protocol. This letter complements the current POLAR protocol. It must be used and filed together with the trial protocol.

New Adverse Drug Reaction of Palbociclib

Based on new findings about Interstitial Lung Disease (ILD)/pneumonitis identified as a new adverse drug reaction of palbociclib, we have distributed a letter with recommendations to the Principal Investigators of the POLAR Trial. Please implement the previously sent recommendations immediately when treating patients with palbociclib. Thank you very much!



Meet the POLAR Team



Meredith Kissel
IBCSG Trial Coordinator/Data Manager

Hi all! My name is Meredith, Trial Coordinator/Data Manager for IBCSG and the POLAR Trial. I am relatively new to IBCSG, as I began my career here in April, 2019. I am so excited to be a part of this team and working on the POLAR Trial. In addition to POLAR, I also currently work on the TOUCH and SOLE Trials. I have a degree in biology and a Master's of Public Health, concentrating in epidemiology. Outside of my professional interests of clinical research, I am an avid sports fan and enjoy cooking, traveling and spending time with my dog, Luna.

POLAR at the IBCSG Annual Meeting Trial Management Workshop 2020

The IBCSG Annual Meeting 2020 is taking place on March 20 – 21 and will welcome research professionals from across the globe to Barcelona, Spain. We hope you can attend!

The IBCSG Annual Meeting also includes our Trial Management Workshop, during which the POLAR Trial will be featured in our breakout sessions. This is a great opportunity to address questions and issues specific to your Center and to share ideas with colleagues. We look forward to seeing you in Barcelona and discussing the POLAR Trial!

Location:
Hotel SB Diagonal Zero Barcelona
Plaça Llevant, s/n, 08019
Barcelona, Spain

Registration link:
[IBCSG Annual Meeting Registration](#)

Annual meeting email:
ibcsg_meeting@ibcsg.org

TMW Group email:
ib.workshop@fstrf.org

