

MyPeBS trial, international randomized study comparing personalized to standard breast cancer screening

(Ref. UNICANCER: Protocol n° UC-0109/1805 - ID RCB: 2018-A00535-50)

MyPeBS (My Personal Breast Screening) is an international randomized clinical trial which compares the benefits of breast cancer screening in a group of women subjected to personalised risk-based screening tests with a control group undergoing current standard planned screening tests, age 40 to 70.

MyPeBS will involve 85,000 women in France, Belgium, Italy, Israel and the UK over a period of 6 years.

Planned mammography or organised screening for breast cancer strategy for women age 40 or 50 and over is controversial, as evidence of efficacy has been challenged. In this context, studying stratified screening on personal risk factors may be an interesting project, however, it should be compared to a "no screening" control group, with appropriate methodology.

The study MyPeBS raises several questions:

1° Lack of a "no screening" arm

Sponsors of the study consider breast cancer screening benefits as firmly established.

Controversy on efficacy is not addressed.

MyPeBS therefore represents a missed opportunity: the opportunity to provide the answer, with current data to the question : Should planned screening tests be continued, be changed to risk-based or stopped ?

To achieve this, there should be another arm in the study : one with no screening.

With the proposed study, it will not be possible to estimate the rate of overdiagnosis i.e. the number of women being diagnosed and treated for a cancer that would have not evolved and never have caused them any problem. Healthy women are directly harmed by overdiagnosis because cancer treatments can be highly toxic or result in permanent disfigurement.

2° A lax approach as to non-inferiority.

According to the official summary of the study, the rate of the most serious forms of cancers (stage 2 and above) will be measured in each group. It should be remembered that the aim of a screening programme is to **reduce** the rate of advanced cancers deaths.

The two groups will be statistically compared with a threshold of "non inferiority" arbitrarily set at 25%. This comparison is somewhat obscure and conceals disconcerting information.

According to the sponsors of the MyPeBS study, in the standard screening group, 480 new cases of severe tumors per 100,000 women are expected to be diagnosed. If the same rate does not exceed 600 per 100,000 women in the new personalised risk-based group, both groups will be declared equivalent. This means that if the rate of serious cancers is increased by less than 25% (for example 18% or 24%), then the study will be considered a success and the researchers will conclude that the new screening methods are "as efficient" as the former ones. In other words, +25% of serious cancers equals zero !

3° Risk level issue

In the individual risk-based group, the risk of breast cancer is evaluated considering age, personal and family history, breast density and genetic background. This risk assessment method has not been fully validated.

Women in the lower risk group will have no screening. However, this subgroup will probably be very small.

Most women will belong to higher risk subgroups and will undergo more mammographies than in the standard screening group. This will specially include women under the age of 50, increasing radiotoxicity concerns.

4° Misleading information

The information booklet provides women with insufficient and misleading information. There is no mention of overdiagnosis and overtreatment which are the major harms of screening, and no mention of the non-inferiority design.

Studying the interest of stratified screening based on risk factors could be useful, but not haphazardly and certainly not with the sole intention of promoting mammography screening one way or the other. This intention is clearly mentioned in Dr Balleyguier's statement, page 14 in the press folder MyPeBS, 28 September 2018: "MyPeBS will probably encourage more women to enter national screening programs. Today, barely one out of two are taking part".

Participants receive partial information on the reduction of mortality through screening, and conflicts of interest of the authors of the protocol are not mentioned.

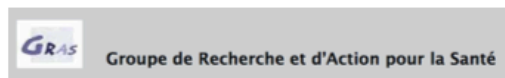
5° Economic issues

Spending on promoting breast cancer prevention would be more appropriate. Even if superiority of personal risk-based screening were to be demonstrated on the frequency of advanced cancers, there would be no reliable evidence of benefits for women in terms of life expectancy or quality-adjusted life year (QALY).

RAISING AWARENESS

The Belgian group GRAS, Italian epidemiologists and scientists of NoGrazie, the French group Cancer Rose and the UK Charity HealthWatch strive to raise awareness that MyPeBS is above all a marketing trial, with no scientific interest for women.

By starting at age 40, when there is no relevance for this age group, using genetic testing lacking scientific support, using more imaging with MRI for "high risk" women and 3D-mammography, MyPeBS promotes technological development and overdiagnosis, the highest risk in screening for women, a risk we should aim to reduce for ethical reasons.



<http://www.gras-asbl.be/>



<http://www.nograzie.eu/>



<https://cancer-rose.fr/>



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