

PRESS RELEASE

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THE LANCET

**THE STANDARD RADIOTHERAPY TREATMENT FOR BREAST
CANCER IS SET TO CHANGE WORLDWIDE**

The final results of the French HypoG-01 study mark a turning point in the treatment of breast cancer on a global scale. Published in [The Lancet](#) after five years of follow-up, this pragmatic non-inferiority study demonstrates that a hypofractionated radiotherapy protocol of 15 sessions over three weeks is no less safe or effective than the standard course of 25 sessions over five weeks for treating breast cancers requiring nodal irradiation. By proving the absence of any increased risk of complications, this French study now establishes itself as the new global therapeutic standard, making it possible to simplify and ease the care pathway for patients. The study was sponsored by Unicancer and coordinated by Dr Sofia Rivera, radiation oncologist and Deputy Head of the Radiotherapy Department at Gustave Roussy, Molecular Radiotherapy and Therapeutic Innovation Laboratory (Inserm/Gustave Roussy/Univ. Paris-Saclay).

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Of the 60,000 new cases of breast cancer diagnosed each year in France, approximately one-third are diagnosed at the locoregional stage, meaning the disease may have spread to the lymph nodes near the breast. For these patients, the standard care pathway had until now consisted of surgery followed by 25 sessions of radiotherapy targeting the breast or chest wall and the nodal area, spread over five weeks.

The HypoG-01 study represents a landmark in breast cancer management: it is the first in the world to provide five-year scientific evidence for this new protocol. Its strength lies in its precision: it confirms the safety of the shorter treatment, even when it is necessary to irradiate the most complex areas, such as the internal mammary chain lymph nodes situated deeper within the chest. Whilst some countries, such as the United Kingdom, had already begun shortening treatment courses, robust international data to validate this practice in these sensitive areas had remained lacking. By now providing this high-level evidence, the French HypoG-01 study dispels the last remaining doubts and establishes itself as the reference for transforming breast cancer care on a worldwide scale.

Reducing duration without compromising oncological safety

The HypoG-01 phase III study, conducted across 29 French hospitals, compared, in women with breast cancer that had spread to the lymph nodes, the safety of a radiotherapy course comprising 15 hypofractionated sessions over three weeks against the standard treatment pathway. The aim was to demonstrate that such a course, two weeks shorter, was no less effective and no more toxic for patients. The authors sought to determine whether concentrating higher doses of radiation per session did not expose women to a greater risk of developing lymphoedema, a side effect of both radiotherapy and surgery that causes swelling of the arm.

In total, 1,265 patients were enrolled in the trial between September 2016 and March 2020, all diagnosed with breast cancer at the locoregional stage. The inclusion criteria for HypoG-01 were fairly broad: patients could present with different breast cancer subtypes, including HER2+, hormone receptor-positive, or triple-negative. *"We aimed to develop a pragmatic trial whose conclusions could be readily applied in routine clinical practice,"* emphasises Dr Sofia Rivera.

Patients were divided into two groups. In the first, they received a hypofractionated radiotherapy schedule comprising 15 sessions over three weeks (total dose of 40 Gy, equivalent to 2.67 Gy per session). In the second group, patients received the standard treatment: 25 radiotherapy sessions over five weeks (total dose of 50 Gy, equivalent to 2 Gy per session).

After five years of follow-up, the final results of HypoG-01, analysed by Professor Stefan Michiels and his team (Oncostat team, Centre for Research in Epidemiology and Population Health — Inserm/Université Paris-Saclay/UVSQ — and Biostatistics and Epidemiology Unit at Gustave Roussy), establish that a three-week radiotherapy course poses no greater risk to patients than the standard five-week course. The risk of developing lymphoedema is virtually identical: 22% for the five-week course and 23% for the three-week course. Likewise, serious side effects are rare and comparable across both arms of the study (2.6%).

The study also provides an answer regarding efficacy. The results show that the three-week protocol is no less effective than the standard treatment at preventing recurrence and ensuring equivalent chances of recovery for patients.

A major advance for the benefit of patients

For patients, the results of the HypoG-01 study mean a significantly lighter care pathway. By reducing radiotherapy from 25 to 15 sessions, the total duration of treatment is cut by 40%, directly reducing fatigue, logistical constraints, and the psychological burden associated with daily sessions, without increasing the risk of side effects. This achievement of French academic research, supported by INCa and Unicancer, thus consecrates a new global reference standard, one that is more humane and more efficient.

"The HypoG-01 study finally delivers the high-level scientific evidence that was lacking internationally to extend short-course treatment to forms of breast cancer requiring nodal irradiation. The publication of these final results in The Lancet is a recognition that acknowledges the excellence of French academic research and confirms that this protocol must henceforth be established as the new global standard. For cancer centres and the entire medical community, this represents a major therapeutic and organisational shift. We demonstrate that it is possible to treat patients just as effectively, but far more quickly, reducing women's treatment pathway by two weeks without any increased risk of complications. Beyond the technical innovation, this is a victory for patient quality of life: we are making treatment less burdensome, less exhausting, and more accessible," concludes Dr Sofia Rivera.

"The fruit of collective work led by Dr Sofia Rivera and the Unitrad cooperative group, HypoG-01 consecrates the excellence of researchers and clinicians at the Centres de Lutte Contre le Cancer, who have been driving innovation and excellence in French oncology for 80 years. This study illustrates the strength and dynamism of the research carried out by the Unicancer network. As the leading academic sponsor of clinical trials in Europe, our ambition is resolutely focused on producing solid and tangible evidence that drives the evolution of standards, for the benefit of all patients, in France and internationally," comments Professor Jean-Yves Blay, President of Unicancer.

Publication

5-year results of hypofractionated locoregional radiotherapy in early breast cancer HypoG-01 (UNICANCER): a French multicentre, randomised, non-inferiority, phase 3, open-label, controlled trial

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About Gustave Roussy

Ranked first in France, first in Europe and sixth in the world, Gustave Roussy is a centre of global expertise entirely dedicated to patients living with cancer. The Institute is a founding pillar of the Paris-Saclay Cancer Cluster. Source of therapeutic innovations and diagnostic breakthroughs, the Institute welcomes nearly 50,000 patients each year, including 3,500 children and adolescents, and develops an integrated approach combining research, care and teaching. An expert in rare cancers and complex tumours, Gustave Roussy treats all cancers at all stages of life. It offers its patients personalised care that combines innovation and humanity, taking into account both care and the physical, psychological and social quality of life. With 4,100 employees at two sites, Villejuif and Chevilly-Larue, Gustave Roussy brings together the expertise essential for high-level cancer research; 32% of treated patients are included in clinical studies. To find out more about Gustave Roussy and follow the Institute's news: www.gustaveroussy.fr/en, [X](#), [Facebook](#), [LinkedIn](#), [Instagram](#) and [Bluesky](#).

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Born from the combined ambitions of universities, grandes écoles, and research organizations, Université Paris-Saclay ranks among the leading European and global universities, covering the fields of Science and Engineering, Life Sciences and Health, and Humanities and Social Sciences. Its scientific policy closely combines research and innovation, expressed in both fundamental and applied sciences to address major societal challenges. From undergraduate to doctoral level, including grandes écoles programmes, Université Paris-Saclay offers a wide-ranging curriculum across a broad spectrum of disciplines, in the service of student success and professional integration. It prepares students for a society in rapid transformation, where critical thinking, agility, and the capacity to continually develop new skills are key. Université Paris-Saclay also offers a rich programme of lifelong learning. Located south of Paris across a vast territory, Université Paris-Saclay benefits from a geographical position that fosters both international visibility and close ties with its socioeconomic partners — major industrial groups, SMEs, start-ups, local authorities, and associations. www.universite-paris-saclay.fr

About Unicancer

Unicancer is France's only hospital network 100% dedicated to fighting cancer and the only national hospital federation specialising in oncology. It brings together France's 18 Centres de Lutte Contre le Cancer (CLCC) — private non-profit institutions — as well as two affiliated members. A major player in research, Unicancer is the leading academic sponsor of clinical trials in oncology in Europe, with more than 120 active studies (national and international), including 50 currently recruiting, sponsored by its R&D directorate. In addition, more than 600 trials are sponsored by the CLCCs themselves. A pioneer in the use of health data, Unicancer has launched, since 2014, five real-world data programmes through its Data and Partnerships directorate, including ESME (109,000 patients), CANTO (13,000+ patients), and OncoDataHub (ODH) (60,000+ patients). Each year, more than 600,000 patients benefit from the latest scientific, therapeutic, and organisational advances in oncology, driven by an agile model combining excellence, humanism, solidarity, and innovation. www.unicancer.fr

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