



# India's first uterus transplant runs into procedural trouble

## ICMR Says Its Permission Wasn't Sought

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**Bengaluru:** While India is proud about its first uterus transplant in Pune last week, the Indian Council of Medical Research (ICMR) has raised some concerns about it.

ICMR spokespersons told TOI that its approval is a must for uterus transplants, regarded as only a research procedure and not medical treatment, but the hospital did not seek permission.

While Pune's Galaxy Care Laparoscopy Institute (GCLI) insists no permission is required for clinical procedures, senior doctors at ICMR state that ICMR permission should be sought both for research and clinical procedures to ensure the patient's safety.

Dr Soumya Swaminathan, director general, ICMR said: "No permission was sought by the Pune-

based hospital before they conducted the first uterus transplant in the country. Till now, ICMR has approved uterus transplant only as an experimental procedure under a research protocol in India. Only a Bengaluru-based facility has been granted this permission."

"According to current guidelines, nobody needs ICMR's permission for any other established procedures apart from the patient's consent to conduct the surgery on him/her. However, when it comes to a uterus transplant the protocol is otherwise. As it is mostly tried as an experimental procedure for research purpose in our country for which permission is granted based on ethical protocols and the transplant involves several risks with only a few procedures emerging to be successful, ICMR's approval is necessary before trying it on any patient," she added.

The protocol required for a uterus transplant includes approval from a registered ethics committee as well as from the ICMR.

However, as reported, Galaxy Care Laparoscopy Institute got a licence only from the state's director

### EXPERT SPEAK

**"This surgery should not be conducted by violating any ethical protocol as local doctors have no experience at all and it will put patients, especially donors, at a very high risk. A similar case in China performed by a top laparoscopy surgeon was a failure**

**Dr Mats Brannstrom** | PROFESSOR  
AND CHAIRMAN AT DEPARTMENT OF  
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rate of health services, but did not get it approved by ICMR.

Dr Shailesh Puntambekar, oncosurgeon and medical director, GCLI said: "ICMR's permission is required only in case of experimental procedures, and not for clinical procedures as informed to me by the ICMR itself. We have approval from the state government; hence, there has been no protocol violation. Several senior doctors from

ICMR were informed about the transplant and following the state government's permission for the transplant, ICMR ensured we could go ahead with the procedure."

"All three patients who have undergone the uterus transplant are doing fine and we've planned a press conference on Saturday. We haven't neglected the patient's safety," he added.

Another senior doctor from ICMR said the Maharashtra government should not have given its approval without ICMR's permission. "In case of other established transplants like kidney, liver and heart, ICMR's permission isn't required and state governments can give direct approval under the Transplant of Human Organs Act (THOA). However, in uterus transplant which is rare, less successful, complicated and risky, ICMR's permission should have been sought to ensure patient's safety," the senior doctor pointed out.

"THOA does not cover novel and research transplants like uterus transplant. In case of novel or research transplants, the safety of the patients must be secured till

completion of the pregnancy and removal of the uterus. The process of a clinical trial under ICMR regulation ensures this safety for participating patients," said Dr Kamini Rao, medical director of Bengaluru-based Milann Fertility Clinic that recently got a nod from ICMR to conduct uterus transplant on two patients as a research procedure.

Milann has tied up with Dr Mats Brannstrom, professor and chairman at department of obstetrics & gynecology, Sahlgrenska Academy, University of Gothenburg and his team after seeking Medical Council of India permission to allow the team to operate in India. Dr Brannstrom had performed the first successful uterus transplant in the world in 2012 and has conducted the procedure on nine women, of which five were successful.

Dr Mats said: "The possible threats to the lives of the recipient as well as the donor are high bleeding and organ rejection during pregnancy and infection. The surgery in the donor takes 10-13 hours and in the recipient 4-6 hours. It is considered the most difficult live donor surgery."