

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:1462
ANSWERED ON:30.07.2003
TRIAL OF RISYUG
ASHOK KUMAR SINGH CHANDEL

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the third and final phase of testing of the male contraceptive `Risyug` has been stopped
- (b) if so, the reasons therefor;
- (c) whether the Government propose to complete the test of this contraceptive in near future and ensure its practical use; and
- (d) if so the details thereof?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI. A. RAJA)

(a)&(b): The Indian Council of Medical Research (ICMR) is coordinating the Restricted Phase-III Clinical trial with Risyug - enrolling 50 subjects each at LNJP Hospital, New Delhi, DDU Hospital, New Delhi and Rural Medicare Centre, New Delhi - which is not a final phase of testing.

An interim data analysis of 63 subjects by the Monitoring Committee, constituted by the Ministry of Health and Family Welfare, have shown some adverse side effects like albumin in urine in 6 cases and in some cases scrotal swelling with pain, scrotal nodules and 4 cases of method failure, one leading to pregnancy.

Based on the above observations, the Monitoring Committee, Toxicological Review Panel of ICMR and a team of Nephrologists from AIIMS, New Delhi, suggested not to induct any new cases and to follow up the recruited cases for long term safety and efficacy.

(c) & (d): After the analysis of raw data of all the 141 subjects who have undergone the test so far and ensuring safety of the Product, full fledged Phase-III clinical trial and reversibility studies with Risyug, will be suggested before its practical use for contraceptive purposes.