Biostudy volunteer in hospital with pneumonia

September 10, 2002, Baroda: Dharmesh Vasava, age 22, one of volunteers for a biostudy carried out by Sun Pharma for the depression medication citalopram, has been admitted to hospital with pneumonia. To the best of the company's knowledge, the infection is not caused by the test medicine nor is the infection caused at the company's labs.

In August this year, Mr Vasava was one of the 14 volunteers for a bioequivalence study for the widely used antidepressant citalopram. He had been explained the trial protocol in local language as per the international good clinical practice (GCP) guidelines, after which he also signed a consent letter, in the local language. He had also been screened using a large number of tests in order to determine whether he was suitable for the study. All case papers required for the study were maintained. The biostudy was done as per the existing rules and regulations in the country.

The bioequivalence study was done in the company's clinical research labs attached to a major hospital in Baroda. The 28 bed clinical lab facilities include ECG, cell analyser ,X Ray, blood chemistry, Urine analyser, Elisa reader, patient monitoring facility and emergency medical facility. A pantry and recreation area is also attached so that volunteers can be kept for 24 hour observation. This facility has been approved by the office of the Drug Controller of India. The center was recently audited by an international auditor prior to applying for international approval. All the required permissions are in place, and GCP and ICH norms are followed. In all, 60 studies involving a total of 650 volunteers have been done at this center, and no volunteer related problems have been reported so far.

During the bioequivalence studies, the company's citalopram brand was compared with the international brand with regard to blood levels, distribution in the body, metabolism and excretion from the body. A single 40mg dose was used, while the maximum dose approved internationally is 60mg.

Citalopram has been in use for more than 5 years and in more than 20 countries with several hundred prescriptions filled. Citalopram is not reported to have caused liver or kidney damage or pneumonia. Citalopram brands, approved by the drug authorities, have been available in the Indian market for more than 7 months now, and no major side effects have been reported.

Mr. Vasava volunteered for this study on August 9 and August 24, along with 13 other people. He was physically examined and found to be in good health before the study. On each date, one puncture was made in a vein, and a vein canula was inserted, from which blood was withdrawn at repeated intervals (totally not exceeding 120ml) as per the protocol of the study.

It was observed that Mr. Vasava had a small inflammation on his hand. The study physician then treated and prescribed him antiinflammatory medicine before discharge- which he may or may not have taken.

Three days after the completion of the study, we understand Mr. Vasava was admitted to the local civil hospital in Bharuch. Since the infrastructure was not adequate to treat him in Bharuch, he was shifted to a private critical care center in Baroda. On humanitarian grounds, the company is paying for his treatment.

He was last reported to be progressing satisfactorily, although still on a ventilator.

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