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## Report finds grave flaws in urology trial

Scandal erupts at Austrian medical school.

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A clinical trial of a stem-cell procedure for urinary incontinence by urologists at the Medical University of Innsbruck, Austria, was full of serious procedural and ethical problems, finds a report by the government's Agency for Health and Food Safety.

The study by Hannes Strasser and his colleagues, to determine the experimental therapy's efficacy, was published last year (*H. Strasser et al. Lancet* 369, 2179–2186; 2007). A partial study was published a few months after (*H. Strasser et al. World J. Urol.* 25, 385–392; 2007).

The agency's report says that the urologists failed to get appropriate approval for the trial from authorities, including an ethics committee, and failed to adequately inform patients about the nature of the procedures and to insure them. Other problems outlined in the report include poor study design, inconsistent handling of patients and failure to randomize patients properly.

The report also says that many of the documents relating to the trials that were presented for inspection may have been forged, including supposed insurance certificates and e-mail correspondence with *The Lancet*.

The therapy involves removing tissue from a patient's arm to create muscle stem cells, then injecting these cells into the same person's urinary sphincter muscle.

Strasser, who is head of the urology department's incontinence division, designed and led the stem-cell project and is implicated throughout the report. The university hospital has now forbidden him from treating patients. But, controversially, the report exonerates the head of the urology department, Georg Bartsch, even though he signed many of the documents related to the therapies and is listed as a co-author on the publications.

Meanwhile, the university rector, Clemens Sorg — who has been outspoken about his intention to act on any scientific misconduct exposed by the inspection, and who asked the



Staff at the Medical University of Innsbruck have been accused of misconduct.

Medical Univ. Innsbruck

Austrian Academy of Sciences to investigate the situation — has been threatened with the sack.

Strasser declined to comment on the case. But he has written an open letter to university authorities denying wrong-doing.

Bartsch, an oncologist, dissociates himself from all parts of the trial, saying that he was unaware of the problems developing until the rector informed him of concerns in November 2007. Although the Lancet paper lists him as one of five co-authors who did “all investigations and treatments”, and includes his signature of agreement, Bartsch insists he did not request authorship but that Strasser included him “in honour of my seniority”. On 31 July Bartsch asked The Lancet to withdraw his name, as “Strasser had not retracted the article as I had suggested”. Bartsch adds that the agency’s report “is not a legal document in any case”.

Bartsch says that ‘honorary authorship’ is given on occasion within his department. He was a member of the university ethics committee until 1997 and, in 2001, he headed an ad hoc committee that oversaw the introduction of ‘good scientific practice’ in the faculty of medicine. Three years later the university’s senate approved a ten-point protocol along these lines, including an explicit rejection of honorary authorship.

The loss-of-confidence motion against Sorg, an immunologist, was brought by the all-powerful university council on 7 July, shortly after the preliminary report was circulated to those involved. The council comprises seven ‘high-standing representatives’ of Austrian society and has the power to dismiss the rector. The council accuses Sorg of a ‘serious breach of duty’, in particular by exposing the university to ‘the danger of serious economic damage’.

But on 28 July, the university senate voted unanimously that the specific concerns put forward by the council were too trivial to warrant dismissal. Sorg has also received a letter of support from top university officials expressing concern about the council’s actions. The council will vote on Sorg’s dismissal at a special meeting on 21 August.

Meanwhile, Austria’s science academy has put its investigation into whether the urologists had followed good scientific practice on hold. “We had the impression that the request came from Sorg as a person, not a university representative,” says Peter Schuster, the academy’s president. “When the problem of Sorg’s possible impeachment came up, we put the case temporarily on ice.”

Sorg, who says that his request was made in an official capacity as a representative of the university, is now under pressure to decide quickly on consequences for Strasser and Bartsch, given that the council may vote to dismiss him within days. As a first step, he asked Strasser to confirm by 18 August that he retracted all relevant papers. Further disciplinary

actions are being considered by Sorg and the head of the university's hospital. Sorg has also asked the council to send its report to the public prosecutor.

In the meantime, several of the hundreds of patients who have undergone the procedure by Strasser's team — within and outside of the trial — claim that they have had serious side effects. Injuries such as sealing of the urinary sphincter and rupture of the bladder have been registered with authorities. **Thomas Juen**, the Innsbruck lawyer who is representing the patients, says: "This is a very grave scandal for the university, and the pressure on the public prosecutor to bring criminal charges will be very high."