

[Redacted]

Subject: A double-blind multicentre study comparing Paroxetine and Fluoxetine in patients with symptoms of anxiety, associated with major depressive disorder.

Date: 23 November 1993

Please find enclosed the letter from [Redacted] regarding the Paroxetine study. According to the letter the Ethics Committee of the [Redacted] New South Wales Centre [Redacted] has decided to cease the enrolments because of the reported cases of suicide gestures, though the number of these cases were thought not to be medication related.

I would like to enclose some information about the Paroxetine study conducted in the [Redacted]

- 25 patients enrolled in the study.
 - 4 patients are currently taking study medication.
 - 16 patients completed the study, 7 patients entered the follow up phase; they have been taking the medication since; none of them are depressed at the moment.
 - 5 patients terminated the study prematurely.
 - 1 committed suicide (Ethics Committee was notified).
 - 3 patients decided to withdraw because of lack of efficacy or unpleasant side effects (nausea, indigestion).
 - 1 patient lived too far from the hospital; she could not keep her appointments.
 - 1 patient took an overdose; she completed the study.
 - 1 patient expressed suicidal ideals, he was admitted to hospital; the patient is still included in the study.
 - 1 patient was admitted to hospital for serious asthma attacks (Ethics Committee was notified in all cases).
- The suicide and suicidal ideas appeared after the patients commenced on medication.

[Redacted]

Kind regards,

[Redacted]