



SPIRIT2

STI571 Prospective International Randomised Trial

Key Facts

- UK Multicentre study (NCRN adopted)
- Looking for 810 patients from UK
- Current status
 - First patient recruited Aug 2008 – Newcastle
 - 0796 patients randomised
- Website: www.spirit-cml.org

Study Summary

- Randomised, Open label
- Newly Diagnosed CML (within 3 months)
- 2 treatment arms (405 patients on each)
 - Arm A: 400mg daily imatinib
 - Arm B: 100mg daily dasatinib
- Primary end point is event-free survival at 5 years
- Secondary endpoints include haematologic and cytogenetic responses

Eligibility - Inclusion Criteria

Key points for pharmacy

1. ≥ 18 years old.
2. Chronic phase

Eligibility - Exclusion Criteria

Key points for pharmacy

1. Prior treatment for CML.
2. Prior chemotherapy (any type).
3. Prior haemopoietic stem cell transplant, either autograft or allograft.
4. Liver or blood clotting problems
5. Uncontrolled medical disease.
6. Another malignancy in the past five years.

Randomisation

1. Done through eCRF.
2. Email alert to site staff registered on eCRF.
3. Screen print from eCRF system.

Study Schedule

Year 1

- Visit 1 – Screening
- Visit 2 – Day 28 (1 month)
- Visit 3 – Day 56 (2 months)
- Visit 4 – Day 84 (3 months)
- Visit 5 – 6 months
- Visit 6 – 9 months
- Visit 7 – 12 months

Years 2 – 5

- Visits 8 – 15
- Visits every 6 months

Treatment Arms

A. 400mg daily imatinib

- No additional supplies required (provided via standard NHS stock)
- A SPIRIT 2 Trial label must be applied
- Drug accountability, etc still required – considered IMP

B. 100mg daily dasatinib

- Dasatinib trial stock (pre-labelled) supplied to hospital pharmacy directly from BMS.
- Initial “float” (50mg & 20mg tablets) sent on site activation
- If patient is randomised to dasatinib, the trial manager will automatically order 3 monthly supply (50mg) for pharmacy.
- Requests for further supplies of 20mg or 50mg tablets should be sent to Trial office using Dasatinib Order Form (on website)

Unused Study Drug should be returned to your hospital and destroyed following your normal hospital procedures. Drug destruction should be recorded on the accountability log.

Pharmacy file

- Information for pharmacists
- Receipt/destruction logs
- Dispensing logs
- Dasatinib IB located on website (file note required)

Where to get information

- Trial Secretary – Wendy Banks

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 Website - www.spirit-cml.org