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MACS news



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We have received local ethics approval from a second site! Rabin Medical Center Petach Tikva, Israel.

Congratulations to Tamar Perri.

Recruitment will soon become our No 1 priority. Do join us as soon as you can!

Recruitment to begin February 15!

We will be arranging to send trial supplies next week (data forms, study drugs etc.) to the centres that have sent us their ethics/IRB approvals, so that they can begin enrolling patients on or after February 15, 2001.

Update on regulatory approvals:

We have received regulatory approval from the Food & Drug Administration in the USA, and expect to get similar approval from Health Canada within the next two weeks.

Collaborators in other countries are reminded that they must comply with their own national governmental regulations as well. We are happy to provide any background information to assist with this.

Local Ethics/IRB approvals:

We have heard from many centres that they are in the midst of this process. If you haven't yet begun, please start soon so that your centre can become an active participant in the trial.





Getting ready for trial participation:

Meet with colleagues

- to confirm their interest
- to assess your centre's ability to recruit and to track patients for the 2 year follow-up

Prepare Ethics/IRB submission

 contact the Data Coordinating Centre (DCC) if you need information or documentation

Plan for study drug storage and dispensing

Complete and return Investigator Agreement to DCC

 provide full contact information for everyone involved in the trial: communication is vital to our success

Return ethics approval to DCC

When your study start-up package arrives

- review the study manual
- make a practice randomisation call (instructions are in the manual)
- contact the DCC with any questions
- begin screening patients
- assess for eligibility
- recruit!







