

Pravara Institute of Medical Sciences (Deemed University)

Ongoing Clinical Trials- 2010-11

Sr. No	Research title	Name of faculty & students	In association / collaboration / Funding details	Budget	Level	Start Date
1.	A randomized, double-blind, placebo-controlled study to evaluate the long-term safety and efficacy of darbepoetin alfa administered at 500 ug once-every-3-weeks in anemic subjects with advanced stage non-small cell lung cancer receiving multi-cycle chemotherapy	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	10,276,178 Lacs	I	Nov 2010
2.	A randomized, multicenter, open-label, phase 3 study to compare the efficacy and safety of panitumumab and cetuximab in subjects with previously treated, wild-type k ras, metastatic colorectal cancer	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	2668987.50 Lacs	I	Jan 2010
3.	A randomized, double-blind, placebo-controlled, multi-center phase 3 study of denosumab as adjuvant treatment for women with early-stage breast cancer at high risk of recurrence (D-CARE)	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	92.5 Lakhs approx	I	May 2010
4.	A multicenter, randomized, double-blind, placebo-controlled study of AGM 785 in skeletally mature adults with a fresh unilateral tibial diaphysial fractures status post definitive fracture fixation with intramedullary nail.	Dr VS Yadkikar Dept. of Orthopaedics	Amgen Incorporation (USA)	5,50,000=00 For 10 patients	I	Nov 2010
5.	Efficacy and safety of hydroxychloroquine in the treatment of type 2 diabetes mellitus : A double blind, Randomized comparison with pioglitazone	Dr. M. Chandurkar	IPCA Mumbai, India	1,00,000=00	N	Feb 2010
6.	Comparative Evaluation of efficacy and safety of fixed dose combination of Tramadol – Paracetamol and Tramadol alone in patients with post operative Orthopedic pain	Dr .K. Vilas Babu	IPCA Mumbai, India	1,00,000=00	N	Feb 2010
7.	Study of acceptability and efficacy of Female condoms a community trial	Dr. K. V. Somasundaram	Cupid India	3.01 Lacs	I	2010

Ongoing Clinical Trials- 2011-12

Sr. No	Research title	Name of faculty & students	In association / collaboration / Funding details	Budget	Level	Start Date
1.	A randomized, double-blind, placebo-controlled study to evaluate the long-term safety and efficacy of darbepoetin alfa administered at 500 ug once-every-3-weeks in anemic subjects with advanced stage non-small cell lung cancer receiving multi-cycle chemotherapy	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	10,276,178 Lacs	I	Nov 2010
2.	A randomized, multicenter, open-label, phase 3 study to compare the efficacy and safety of panitumumab and cetuximab in subjects with previously treated, wild-type k ras, metastatic colorectal cancer	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	2668987.50 Lacs	I	Jan 2010
3.	A randomized, double-blind, placebo-controlled, multi-center phase 3 study of denosumab as adjuvant treatment for women with early-stage breast cancer at high risk of recurrence (D-CARE)	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	92.5 Lakhs approx	I	May 2010
4.	A multicenter, randomized, double-blind, placebo-controlled study of AGM 785 in skeletally mature adults with a fresh unilateral tibial diaphyseal fractures status post definitive fracture fixation with intramedullary nail.	Dr VS Yadkikar Dept. of Orthopaedics	Amgen Incorporation (USA)	5,50,000=00 For 10 patients	I	Nov 2010

Ongoing Clinical Trials- 2012-13

Sr. No	Research title	Name of faculty & students	In association / collaboration / Funding details	Budget	Level	Start Date
1.	A randomized, double-blind, placebo-controlled study to evaluate the long-term safety and efficacy of darbepoetin alfa administered at 500 ug once-every-3-weeks in anemic subjects with advanced stage non-small cell lung cancer receiving multi-cycle chemotherapy	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	10,276,178 Lacs	I	Nov 2010
2.	A randomized, multicenter, open-label, phase 3 study to compare the efficacy and safety of panitumumab and cetuximab in subjects with previously treated, wild-type k ras, metastatic colorectal cancer	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	2668987.50 Lacs	I	Jan 2010
3.	A randomized, double-blind, placebo-controlled, multi-center phase 3 study of denosumab as adjuvant treatment for women with early-stage breast cancer at high risk of recurrence (D-CARE)	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	92.5 Lakhs approx	I	May 2010
4.	A multicenter, randomized, double-blind, placebo-controlled study of AGM 785 in skeletally mature adults with a fresh unilateral tibial diaphysial fractures status post definitive fracture fixation with intramedullary nail.	Dr VS Yadkikar Dept. of Orthopaedics	Amgen Incorporation (USA)	5,50,000=00 For 10 patients	I	Nov 2010
5.	To study the safety and efficacy of R-HSC-001 in patients with spinal cord injury	Dr. V.S.Yadkikar	Reliance Life Sciences, Mumbai	4.93 Lacs	N	2012
6.	To study the safety and efficacy of ReliDerm (R)DT in patients with chronic diabetic foot ulcer	Dr. M. Chadurkar	Reliance Life Sciences, Mumbai	2.21 Lacs	N	2012

Ongoing Clinical Trials- 2013-14

Sr. No	Research title	Name of faculty & students	In association / collaboration / Funding details	Budget	Level	Start Date
1.	A randomized, double-blind, placebo-controlled study to evaluate the long-term safety and efficacy of darbepoetin alfa administered at 500 ug once-every-3-weeks in anemic subjects with advanced stage non-small cell lung cancer receiving multi-cycle chemotherapy	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	10,276,178 Lacs	I	Nov 2010
2.	A randomized, multicenter, open-label, phase 3 study to compare the efficacy and safety of panitumumab and cetuximab in subjects with previously treated, wild-type k ras, metastatic colorectal cancer	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	2668987.50 Lacs	I	Jan 2010
3.	A randomized, double-blind, placebo-controlled, multi-center phase 3 study of denosumab as adjuvant treatment for women with early-stage breast cancer at high risk of recurrence (D-CARE)	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	92.5 Lakhs approx	I	May 2010

Ongoing Clinical Trials- 2014-15

Sr. No	Research title	Name of faculty & students	In association / collaboration / Funding details	Budget	Level	Start Date
1.	A randomized, double-blind, placebo-controlled, multi-center phase 3 study of denosumab as adjuvant treatment for women with early-stage breast cancer at high risk of recurrence (D-CARE)	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	92.5 Lakhs approx	I	May 2010
2.	A randomized, double-blind, placebo-controlled study to evaluate the long-term safety and efficacy of darbepoetin alfa administered at 500 ug once-every-3-weeks in anemic subjects with advanced stage non-small cell lung cancer receiving multi-cycle chemotherapy	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	10,276,178 Lacs	I	Nov 2010
3.	A Randomized, Open label, Active controlled, Phase II/III Clinical study to Assess the safety and immunogenicity of SIIL's purified Vero Cell Rabies Vaccine (PVRV) in Patients with Potential Rabies Exposure	Dr. Amol Hartalkar Dept. of Medicine	Serum Institute, Pune	2,04,000 = 00	N	May 2014
4.	Prospective, multi-centric, open label, two arm, parallel group, active control, randomized, comparative clinical study to evaluate efficacy and safety of R-TPR-029/Neulasta®(Neulastim®) when given subcutaneously in patients with Chemotherapy Induced Neutropenia. (Protocol No: RLS/TP/2011/01	Dr K K Singh, Professor & HOD Dept. of Oncology	Reliance Life Sciences	7,62,125 = 00 for 5 patients 1,52,425 = 00 / patients	N	Dec 2014
5.	A phase IV, Multi-centric clinical trial to systematically evaluate safety, reactogenicity and tolerability of trivalent, Live attenuated seasonal influenza vaccine of SIIL in large population	Dr Prashant Nigvekar Professor Dept. of Pediatrics, PIMS-DU	Serum Institute, Pune	11,00,000=00 (For 200 Patients) 5500/patient Amount received till date 179190=00	N	July 2015

Ongoing Clinical Trials- 2015-2016

Sr. No	Research title	Name of faculty & students	In association / collaboration / Funding details	Budget	Level	Start Date
1.	A randomized, double-blind, placebo-controlled, multi-center phase 3 study of denosumab as adjuvant treatment for women with early-stage breast cancer at high risk of recurrence (D-CARE)	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	92.5 Lacs		May 2010
2.	A randomized, double-blind, placebo-controlled study to evaluate the long-term safety and efficacy of darbepoetin alfa administered at 500 ug once-every-3-weeks in anemic subjects with advanced stage non-small cell lung cancer receiving multi-cycle chemotherapy	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	102.76 Lacs		Nov 2010
3.	A phase IV, Multi-centric clinical trial to systematically evaluate safety, reactogenicity and tolerability of trivalent, Live attenuated seasonal influenza vaccine of SIIL in large population	Dr Prashant Nigvekar Professor Dept. of Pediatrics, PIMS-DU	Serum Institute, Pune	11,00,000=00 (For 200 Patients) 5500/patient Amount received till date 179190=00	N	July 2015
4.	A Multicenter prospective community-based surveillance to estimate the burden of rotavirus gastroenteritis in children \leq 24 months of age in India.	Dr A P Kulkarni Professor Dept. of PSM RMC Loni.	Shantha Biotechnics Pvt. Ltd, Hyderabad	16,24,000=00	N	Oct 2015
5.	Quantification of total circulating cell-free DNA as a screening/ diagnostic tool for cancer.	Dr. Vandana Jain HOD, Dept. of Radiotherapy, RMC, PIMS, Loni.	Datar Genetics, Nashik	9 Lacs	N	Sept. 2016
6.	A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer	Dr. Nikam Bhushan Manohar Department of Oncology & Radiotherapy	Sun Pharma, Mumbai	1 Lac / Patients	N	Sept. 2016

Ongoing Clinical Trials- 2016-2017

Sr. No	Research title	Name of faculty & students	In association / collaboration / Funding details	Budget	Level	Start Date
1.	A randomized, double-blind, placebo-controlled, multi-center phase 3 study of denosumab as adjuvant treatment for women with early-stage breast cancer at high risk of recurrence (D-CARE)	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	92.5 Lacs		May 2010
2.	A randomized, double-blind, placebo-controlled study to evaluate the long-term safety and efficacy of darbepoetin alfa administered at 500 ug once-every-3-weeks in anemic subjects with advanced stage non-small cell lung cancer receiving multi-cycle chemotherapy	Dr Satish Sonwane Dept. of Surgery	Amgen Incorporation (USA)	102.76 Lacs		Nov 2010
3.	Quantification of total circulating cell-free DNA as a screening/ diagnostic tool for cancer.	Dr. Vandana Jain HOD, Dept. of Radiotherapy, RMC, PIMS, Loni.	Datar Genetics, Nashik	9 Lacs	N	Sept. 2016
4.	A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer	Dr. Nikam Bhushan Manohar Department of Oncology & Radiotherapy	Sun Pharma, Mumbai	1 Lac / Patients	N	Sept. 2016