

Bal Raj Bhandari, MD

PERSONAL DATA:

Residence: 3206 Lake Desiard Drive
Monroe, Louisiana 71201
Date of Birth: November 1, 1961
Place of Birth: Granby, Quebec, Canada
Marital Status: Married

CERTIFICATION:

2005 Education American Board of Internal Medicine – Gastroenterology Recertification
2003 American Board of Physician Nutrition Specialist
1995 Board Certified, Gastroenterology
1994 U.S. Medical Licensing Exam; Part 1, 2, and 3
1994 Board Certified, Nutrition
1992 Diplomat American Board of Internal Medicine
1988 Licensing examination of Medical Colleges of Canada

EDUCATION:

September 2003
How to Coordinate Clinical Trials: The Basics
Houston, Texas
July 1, 1992 – June 30, 1995
Fellowship in Gastroenterology and Nutrition
Winthrop University Hospital - Minneola, New York
January 1, 1992 – June 30, 1992
Chief Medical Resident
Our Lady of Mercy Medical Center - Bronx, New York
January 1, 1989 – December 31, 1991
Internal Medicine Residency
Our Lady of Mercy Medical Center - Bronx, New York
September 1983 – May 1987
Graduate Medical Education
The University of Ottawa Medical School - Ottawa, Ontario, Canada
September 1978 – May 1983
Undergraduate Education - BSC Chemistry (Honors)
The University of Ottawa - Ottawa, Ontario, Canada

EMPLOYMENT:

2002 – Present
Delta Research Partners, LLC
608 Grammont Street, Monroe, LA 71201
Title: Principal Investigator
1998 – Present
Endoscopy Center of Monroe
316 South 6th Street, Monroe, LA 71201
Title: Staff Physician
July 1995 – Present
Gastroenterology and Nutritional Medical Services
616 South Washington Street, Bastrop, LA
Private Practice

FACULTY APPOINTMENTS:

July 1992
Preceptor – Introduction to Clinical Medicine
SUNY Health Center at Stony Brook - Stony Brook, New York
January 1992 – July 1992
Chief Medical Resident
1989 – 1992
Assistant Clinical Instructor

HONORS AND AWARDS:

September 1997
Named Spokesperson for the American Liver Foundation in Northeast Louisiana by Governor M. J. “Mike” Foster
1979, 1980, 1982, 1983
Dean’s List – University of Ottawa: Ottawa, Ontario, Canada

PRESENTATION:

1992 - 1995
Staff - Lecturer-Core Lecture Series to the House
Winthrop University Hospital
Minneola, New York
1992
Medical Grand Rounds
Our Lady of Mercy Medical Center
Bronx, New York

AFFILIATION:

American Board of Physician Nutrition Specialists
American Gastroenterology Association
American Society of Gastrointestinal Endoscopy
American College of Physicians

PUBLICATIONS:

1. C. Difficile in a Community Hospital: Badiga, M.; Bhandari, Raj; Pitchimoni, C.S.: *Gastroenterology*, 1991; 100:A405
2. Na-glucose Transport is Impaired in Villus Electrocytes of Chronically Inflamed Rabbit Ileum : C.S. Hyun; L.A. Martello; C.W.P. Chen; Raj Bhandari; S. Teichberg: *Gastroenterology*, 1994; 106:A239
3. Phorbol Ester-Induced CI Secretion in Rabbit Ileum is Associated with Translocation of PkC-isoform: Raj Bhandari, L.A. Martello, C.S. Hyun: *Gastroenterology*, 1994; 106:A222
4. Combined Treatment with Postnasal drainage: YAG Laser and Absolute Ethanol Injection compared to Nd: YAG Laser Therapy Alone in Malignant Esophageal and Rectal Obstruction: Raj Bhandari, B. Banerjee: submitted to *GI Endoscopy*
5. Current Management of Secretory Diarrhea, A Review: Raj Bhandari; R. Burakoff; accepted for Spring Issue, *The Gastroenterologist*
6. Mechanism of PDG-Induced CI Secretion in the Distal Rabbit Ileum; R. Bhandari, L. Martello, C.S. Hyun, submitted to *AJP*
7. Alteration of Enterocyte Na-glucose Co-transporter (SGLT-1) in Chronic Inflammation: C. Hyun, R. Bhandari, et al, submitted to *AJP*
8. Chronic Inflammation Induces Alteration in the Zonula Occludens (ZO) and Lateral Junctional Strands of Mucosal Epithelial Cells in Rabbit Ileum: C.S. Hyun, R. Bhandari, et al, submitted as abstract to *Gastroenterology*, 1995.

PUBLICATIONS (Continued):

9. Protein Kinase-C (PKC)-Medicated Chloride Section is Cl/HCO_3 -Dependent in Rabbit Ileum: R. Bhandari, C. Hyun, submitted as abstract to *Gastroenterology*, 1995
10. Rifaximin has a Favorable Long-Term Safety profile for maintenance of Remission from Overt Hepatic Encephalopathy: M. Sheikh, N. Bass, A. Sanyal, F. Poordad, K. Mullen, S. Sigal, T. Fredrick, R. Bhandari, R. Vemura, S. Huang, K. Merchant, A. Shaw, E. Bortey, W. Forbes, submitted as abstract to *ACG*, June 2009.
11. Rifaximin has a Favorable Long-Term Safety Profile for Maintenance of Remission from Overt Hepatic Encephalopathy: M. Sheikh, N. Bass, A. Sanyal, F. Poordad, K. Mullen, S. Sigal, T. Fredrick, R. Bhandari, R. Vemura, S. Huang, K. Merchant, A. Shaw, E. Bortey, W. Forbes, submitted as abstracts for *The 74th Annual Scientific meeting of the American College of Gastroenterology: The American Journal of Gastroenterology*, October 2009.
12. Safety, tolerability and preliminary activity of GS-9450, a selective caspase inhibitor, in patients with non-alcoholic steatohepatitis (NASH): P.V. Ratziu, M. Chojkier, M. Sheikh, A. Sanyal, J. Lim, H. Conjeevaram, N. Chalasani, M. Abdelmalek, Al. Bakken, C. Renou, M. Palmer, R.A. Levine, R. Bhandari, M. Cornpropst, W. Liang, B. King, E. Mondou, F.S. Rousseau, pending submission as an abstract for the *EASL 2010*.
13. **"Rifaximin Decreases Venous Ammonia Concentrations and Time-Weighted Average Ammonia Concentrations Correlate with Overt Hepatic Encephalopathy (HE) as Assessed by Conn Score in a 6-Month Study"** has been accepted for **POSTER PRESENTATION** at the International Liver Congress™ 2010 by EASL, taking place in Vienna, Austria, April 14-18, 2010.
14. Category 2b. Cirrhosis and its Complications: b. Clinical Aspects: Poster Board Number 195 Rifaximin decreases venous ammonia concentration and time-weighted average ammonia concentrations correlate with overt Hepatic Encephalopathy (HE) as assessed by CONN Score in a 6-month study.
15. A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of GS-9450 in Patients With Nonalcoholic Steatohepatitis: V. Ratziu, M. Sheikh, A. Sanyal, J. Lim, H. Conjeevaram, N. Chalasani, M. Abdelmalek, A. Bakken, C. Renou, M. Palmer, R. Levine, B. Bhandari, M. Cornpropst, W. Liang, B. King, E. Mondou, F. Rousseau, J. McHutchison, M. Chojkier, submitted as a manuscript to the journal *Hepatology*.

RESEARCH EXPERIENCE:

September 2003

How to Coordinate Clinical Trials: The Basics - Houston, Texas

Co-Investigator of three Hepatitis-C Studies:

1. Dr. Ira Jacobson study: Comparison of PEG Interferon Alfa-2B plus Ribavirin given as a fixed dose for on a weight optimized basis for treatment of chronic hepatitis-C in previously untreated adult subjects.
2. A randomized multi-center trial comparing induction PEG-Intron-A plus Ribavirin versus PEG Intron-A plus Ribavirin in patients who have previously not responded or have relapsed following Intron-A based therapy for chronic hepatitis-C, with maintenance therapy for patients who continue to remain non-responsive. Principal investigator: Eric Lawiz, M.D., Gastroenterology Clinic, Brooke Army Medical Center.
3. Consultant for Rebtron Compliance Assessment Program Survey (the "ReCAP Survey") being conducted by Ingenix Pharmaceutical Services for Schering Corporation.

Investigator:

1. Limited access protocol for the use of oral cisapride in the treatment of refractory Gastroesophageal reflux disease (GERD) and other gastrointestinal motility disorders

2004 Clinical Studies:

1. Aquavan Injection: A Phase III, randomized, open-label study to assess the safety and efficacy of AQUAVAN Injection versus Midazolam HCl for sedation in patients undergoing colonoscopy procedures.
2. A Phase 2b study of merimepodib in combination with pegylated interferon alfa-2a (Pegasys) and Ribavirin in subjects with chronic genotype I hepatitis-C non-responsive to prior therapy with pegylated interferon alfa and ribavirin.
3. A Phase 2b multicenter, randomized, double-blind, placebo-controlled, parallel group, dose-ranging study of YM443 in subjects with functional dyspepsia
4. A 12-week, randomized, double-blind, placebo-controlled study with PRN BID and fixed Dosing regimens of Alosetron in Female Subjects with severe diarrhea-predominant irritable bowel syndrome who have failed conventional therapy.

2005 Clinical Studies:

1. A 12-week, multicenter, double-blind, randomized efficacy and safety study of LUBIPROSTONE in subjects with constipation-predominant Irritable Bowel Syndrome.
2. A randomized, double-blind, dose-response study to assess the efficacy and safety of AQUAVAN Injection for procedural sedation in patients undergoing colonoscopy.
3. A multicenter, randomized, double-blind, placebo-controlled study of efficacy and safety of ITOPRIDE HCl in patients suffering from functional dyspepsia.
4. A multicenter, open-label study to evaluate the long-term safety and efficacy of ITOPRIDE HCl in patients suffering from functional dyspepsia.
5. A multicenter, randomized, blinded, placebo controlled, cross-over study to investigate the safety and tolerability of intravenous VIT-45 in patients with Iron Deficiency Anemia.
6. A Phase II randomized, double-blind, placebo controlled, parallel group, multicenter study to evaluate the efficacy and safety of a four-week treatment with ATI-7505 for the healing of acute erosive esophagitis.
7. A Phase II randomized, double-blind, placebo controlled, parallel group, multicenter study to evaluate the efficacy and safety of a four-week treatment with ATI-7505 for the relief of heartburn symptoms in patients with symptomatic Gastroesophageal Reflux Disease (GERD)-Amendment 1.

2006 Clinical Studies:

1. Comparison of weight-based doses of Taribavirin combined with peginterferon Alfa-2b versus Ribavirin combined with peginterferon Alfa-2b in therapy-naïve patients with Chronic Hepatitis C Virus Genotype 1 Infection.
2. Non-responsive to prior therapy and Pegylated Interferon Alfa and Ribavirin.
3. The safety and efficacy of hematinic agent in the treatment of postpartum patients.

2007 Clinical Studies:

1. A randomized, double-blind phase 3 study of the efficacy and safety of HZT-501 in subject requiring NSAID treatment.
2. A double-blind follow-on safety study of HZT-501 in subjects who have completed participation in Horizon Protocol HZ-CZ-301 or Horizon Protocol HZ-CA-303.
3. A randomized, double-blind, placebo-controlled, multi-national study to determine the effect of Cellegesic Nitroglycerin Ointment 0.4% on the pain associated with a chronic anal fissure.
4. A multi-center, randomized, double-blind, placebo-controlled trial to evaluate the efficacy, safety and tolerability of Rifaximin 550 mg BID for 6 months in preventing Hepatic Encephalopathy.
5. A multi-center, open-label trial to evaluate the long-term safety and tolerability of Rifaximin 550 mg BID in subjects with a history of Hepatic Encephalopathy.
6. A multi-center, Investigator-blinded, randomized, 12-month, parallel-group, non-inferiority study to compare the efficacy of 1.6 to 2.4g Asacol® therapy QD divided dose BID in the Maintenance of Remission of Ulcerative Colitis.
7. A 52 week, randomized, double-blind, double-dummy, placebo-controlled study to assess the safety and efficacy of a 12-week treatment of Acute Diverticulitis with Asacol® 2.4g/day (400mg Mesalamine tablet), followed by a 9 month treatment-free observation period.
8. Procurement of blood samples for use in the development of a gastrointestinal disease test panel.
9. A safety and efficacy evaluation of BLI-008 Oral Sulfate Solution vs. MoviePrep® as bowel cleansing preparations in adult subjects.
10. Clinical efficacy and safety of MAX-002 vs. Canasa® in the treatment of mild to moderate ulcerative proctitis: a multicenter, open-label, randomized, parallel group, non-inferiority study.
11. A phase II, randomized, adaptive design, multicenter, parallel group, placebo-controlled, 58 day, dose-ranging study of ATI-7505 in patients with Postprandial Distress Syndrome.
12. A randomized, multi-center, double-blind, placebo-controlled, dose-range-finding, parallel group, Phase 2 trial of Oral Linaclotide Acetate Administered to patients with Chronic Constipation.
13. A randomized, multi-center, double-blind, placebo-controlled, dose-range-finding, parallel-group, Phase 2 trial of Oral Linaclotide Acetate Administered to patients with Irritable Bowel Syndrome with Constipation.
14. A Phase 2, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of three different doses (275, 550, 1100mg) of Rifaximin associated irritable bowel syndrome.
15. A randomized, double-blind, placebo-controlled multicenter Phase II/III study to evaluate the efficacy and safety of tegaserod and placebo given orally for 12 weeks for the treatment of Opioid-Induced Constipation in patients with Chronic Non-Cancer Pain.
16. A 52-week extension to study CHTF919N2201 to evaluate the safety and efficacy of tegaserod (6mg BID and 12mg BID OD) given orally for the treatment of Opioid-Induced Constipation in patients with Chronic Non-Chronic Pain.
17. A randomized, double-blind, placebo-controlled, multicenter evaluation of the efficacy and safety of tegaserod 6mg BID administered orally for 12 weeks, to patients with Chronic Constipation, aged 65 or older.

2008 Clinical Studies:

1. A multi-center, randomized, controlled study to investigate the safety dose of intravenous Ferric Carboxymaltose (FCM) vs. Standard Medical Care in treating Iron Deficiency Anemia in subjects who are not Dialysis dependant.
2. A multi-center, randomized, controlled study to investigate the safety and tolerability of Intravenous Ferric Carboxymaltose (FCM) vs. Standard Medical Care in treating Iron Deficiency Anemia.
3. A Phase 2 multi-center, randomized, placebo-controlled, double-blind study to evaluate the Safety and Efficacy of Golimumab maintenance therapy, administered subcutaneously, in subjects with moderately to severely active Ulcerative Colitis.
4. A Phase 3 multi-center, randomized, placebo-controlled, double-blind study to evaluate the Safety and Efficacy of Golimumab maintenance therapy, administered subcutaneously, in subjects with moderately to severely active Ulcerative Colitis.
5. A Safety and efficacy evaluation of BLI850 vs. HalfLytely® and Bisacodyl Bowel prep kit as Bowel Cleansing preparation in adult subjects.
6. A phase IIIb, multinational, randomized, double-blind, placebo-controlled trial to assess the efficiency and safety of certolizumab pegol, a pegylated Fab' fragment of a humanized anti-TNF- alpha monoclonal antibody, administered subcutaneously at weeks 0, 2 and 4 in subjects with moderately to severely active Crohn's disease.
7. A phase IIIb, multinational, open-label, follow-on trial to C87085 designed to assess the long-term safety of certolizumab pegol, a pegylated Fab' fragment of a humanized anti-TNF-alpha monoclonal antibody, administered at weeks 0, 2, and 4, and then every 4 weeks thereafter, in subjects with moderately to severely active Crohn's disease who have participated in study C87085.
8. A randomized, double-blind, placebo-controlled study of AGI-003 (Averapamil) in the treatment of Irritable Bowel Syndrome with Diarrhea (IBS-D).
9. An open-label, roll-over safety study of AGI-003 (Averapamil) in the treatment of Irritable Bowel Syndrome with Diarrhea (IBS-D)
10. A phase 3, randomized, double-blind, placebo-controlled, multi-center study to assess the efficacy and safety of Rifaximin 550mg TID in the treatment of subjects with Non-Constipation Irritable Bowel Syndrome
11. A multi-center, randomized, placebo-controlled, double-blinded study of the efficacy and safety of Lubiprostone in patients with Opioid-induced bowel dysfunction.
12. Validation of patient-reported outcome measures for the assessment of GERD symptoms and their subsequent impact on patients with a partial response to PPI treatment in a two part multi-center phase IIA study including a four week randomized double-blind, placebo-controlled parallel- group treatment period with AZD3355, 65 mg BID as add-on treatment of PPI.
13. A phase 3, randomized, double blinded, placebo-controlled, parallel-group Trial of Linaclotide administered orally for 12 weeks followed by a 4-week randomized withdrawal period in patients with Chronic Constipation.
14. An Open-label, long term safety study of oral Linaclotide administered to patients with Chronic Constipation or Irritable Bowel Syndrome with Constipation.

2009 Clinical Studies

1. A phase 3, randomized, double-blind, placebo-controlled, parallel-group trial of Linaclotide administered orally for 26 weeks in patients with Irritable Bowel Syndrome with Constipation.
2. A phase 2, multi-center, randomized, double-blind, placebo-controlled, dose-ranging trial to evaluate the efficacy safety and tolerability of AST-120 (Spherical Carbon Absorbent) for 8 weeks in the treatment of mild hepatic encephalopathy.
3. A Dose-Response Efficacy and safety Study of Arbaclofen Placarbil (XP19986) as Adjunctive Therapy in Subjects with Gastroesophageal Reflux Disease (GERD) who are Incomplete Responders to a Proton Pump Inhibitor (PPI).
4. A Phase IIb, Double-blind, Randomized, Placebo-controlled, Multi-centre, Dose-finding Efficacy and Safety Study of a Range of Doses of A3309 in Patients with Chronic Idiopathic Constipation.
5. A Multi-center, Randomized, Active Controlled Study to Investigate the Efficacy and Safety of Intravenous Ferric Carboxymaltose (FCM) in Patients with Iron Deficiency Anemia (IDA).
6. Collection of Blood Samples for the Discovery of Biomarkers Associated With Irritable Bowel Syndrome.
7. A Double-Blind, Double-Dummy, Randomized, Active-Comparator, Arthritis Non-Inferiority Study of LT-NS001 versus Naprosyn for Twelve Weeks in Osteoarthritis Patients to Compare Endoscopic Gastric Ulcer Rates.

2010 Clinical Studies

1. A Multicenter, Randomized, Double-blind, Placebo-controlled, parallel group, dose-ranging clinical study to evaluate the efficacy and safety of metoclopramide nasal spray solution in Diabetic subjects with Gastroparesis
2. A Randomized, Double-blind, Placebo-controlled, parallel-group, Dose-ranging, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-27018966 in the Treatment of Patients with Irritable bowel Syndrome with Diarrhea.
3. A Randomized, Double-blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of GSK1605786A in the Treatment of Subjects with Moderately-to-Severely Active Crohn's Disease.
4. A Randomized, Double Blind, Placebo-Controlled Study to Investigate the Efficacy and safety of GSK1605786A in The Maintenance of Subjects with Crohn's Disease.
5. An Open-Label Extension Study to Assess the Safety of GSK16057A in Subjects with Crohn's disease
6. Linaclotide Long Term safety Study Follow-up participant Interviews.

2011 Clinical Studies

1. A Multicenter, 1-Week, Double-Blind, Randomized, Placebo-Controlled Trial Comparing the Lubiprostone 24-ug capsule formulation (Apotex, Inc) with Amitiza (lubiprostone) 24-ug capsule formulation (Sucampo Pharma Americas, Inc. and Takeda Pharmaceutical America, Inc) in Subjects with Chronic Idiopathic Constipation.

REFERENCES:

Available upon request