

VOLUNTEER MEDICAL RESEARCH
3221 Tamiami Trail, 2nd Floor, Port Charlotte, FL 33952
Ph. (941) 258-3556 Fax (941) 258-3558

CV for Dr. Rohit Pankhaniya, MD

EMPLOYMENT:

2008 – Present	Coastal Nephrology Associates 3221 Tamiami Trail Port Charlotte, Florida 33952
11/2017-Present	Medical Director Fresenius Kidney Care 2020 Tamiami Trail Port Charlotte, FL 33948
2008 – 2012	Kidney Disease & Hypertension Center, P.A. 155 Second Ave., Suite 1100 St. Petersburg, FL 33701
2007 – 2008	Southwest Kidney Institute, PLC 5750 W. Thunderbird, Suite G-700, G-760 Glendale, Arizona 85306-4673
2007 – 2007	Nephrology: Locum Tenens VA Medical Center Tucson, Arizona
2005 – 2006	Nephrologist Mid Michigan Physicians 1540 Lake Lansing Rd Ste 103 Lansing, MI 48912
2002 – 2007	House Physician Grosse Pointe House Physicians Grosse Pointe Woods, Michigan

EDUCATION:

Special Training 2005	Training in Vascular Access Procedures at Emory University Atlanta, Georgia
--------------------------	--

FELLOWSHIP:

2002-2005	Clinical and Research Fellowships, Department of Nephrology Henry Ford Hospital, Detroit, Michigan
-----------	---

RESIDENCY:

2001 – 2002	Chief Medical Resident, Wayne State University Detroit Medical Center, Detroit, Michigan
1998 – 2001	Internal Medicine Residency, Detroit Medical Center Wayne State University, Detroit, Michigan

VOLUNTEER MEDICAL RESEARCH
3221 Tamiami Trail, 2nd Floor, Port Charlotte, FL 33952
Ph. (941) 258-3556 Fax (941) 258-3558

CV for Dr. Rohit Pankhaniya, MD

1995 – 1998 Relocation to the United States of America
Preparation for US Medical Licensing Examination (USMLE)

1994 – 1995 Sardar Patel University Hospital, Karamsad, India
Clinical Tutor in Pathology

1994 Sardar Patel University Hospital, Karamsad, India
House Officer in Psychiatry

1994 Sardar Patel University Hospital, Karamsad, India
House Officer in Internal Medicine

INTERNSHIP:

1992-1993 Sadar Patel University Hospital, Karamsad, India

1987-1992 Bachelor of Medicine and Bachelor of Surgery (M.B.B.S.)
Pramukhswami Medical College
Sardar Patel University, Karamsad, India

BOARD CERTIFICATION:

2005 American Board of Internal Medicine
Certificate Number: 208275
Specialty: Nephrology

2001 American Board of Internal Medicine
Certificate Number: 208275
Specialty: Internal Medicine

MEDICAL LICENSURE:

02/2007 Board of Internal Medicine Examiners of the state of Florida
Certificate Number: ME98038
Original date of issue: 20 Feb 07

HOSPITAL AND MEDICAL STAFF AFFILIATIONS:

2008 – Present Bayfront Health Punta Gorda
809 E. Marion Avenue
Punta Gorda, FL 33950

Bayfront Health Port Charlotte
2500 Harbor Boulevard
Port Charlotte, FL 33952

Fawcett Memorial Hospital
21298 Olean Boulevard
Port Charlotte, FL 33952

VOLUNTEER MEDICAL RESEARCH
3221 Tamiami Trail, 2nd Floor, Port Charlotte, FL 33952
Ph. (941) 258-3556 Fax (941) 258-3558

CV for Dr. Rohit Pankhaniya, MD

2011-Present Englewood Community Hospital
700 Medical Boulevard
Englewood, FL 34223

2013- Present Venice Regional Bayfront Health
540 The Rialto
Venice, FL 34285

HONORS AND AWARDS

2012- Present Castle Connolly “Top Doctors Award”
2014- Present Vice Chairman, Bayfront Health Port Charlotte
2017- Present Chief of Staff, Bayfront Health Port Charlotte

PROFESSIONAL PRESENTATIONS:

Presentation – Regional ACP-ASIM Meeting, MI: Paraneoplastic
Neurological Manifestation of Hepatocellular Carcinoma,
Pankhaniya R., Girgis R., September 22, 2000

PROFESSIONAL AFFILIATIONS:

2000 – Present Association of American Physician of Indian Origin
2002 – Present American Society of Nephrology
2002 – Present Renal Physician Association
2017- Present ACO Administrator Bayfront Health Port Charlotte
2017- Present NOVA Southeastern University (Preceptor for Physicians Assistant
Program)
2016- Present Medical Advisory Board, Entresto

PUBLICATIONS:

Biderman J., Edgar V., Pankhaniya R., Yee J., Cortes P.,: Effects of
Sulfonylhureas on Glomerulosclerosis in Type 1 and Type 2 Models
Of Diabetes KI: 2005

RESEARCH EXPERIENCE AND TRAINING:

CURRENT GCP training, CITI
2010 Clinical Research Training for Physicians
Memorial Hospital & Encore Research Group, LLC
2010 National Institute of Health GCP Training

2008 – Present Investigator
Volunteer Medical Research
3221 Tamiami Trail, 2nd Floor
Port Charlotte, FL 33952

VOLUNTEER MEDICAL RESEARCH
3221 Tamiami Trail, 2nd Floor, Port Charlotte, FL 33952
Ph. (941) 258-3556 Fax (941) 258-3558

CV for Dr. Rohit Pankhaniya, MD

RESEARCH PROTOCOLS

2018-Continuing PI: Rohit Pankhaniya Reata PHOENIX Protocol: 402-C-1702
A Phase 2 Trial of the Safety and Efficacy of Bardoxylone Methyl in Patients with Rare Chronic Kidney Diseases

2017-Continuing PI: Kianoosh Kaveh Kadmon Protocol: KD019-211
A Double-blind Randomized Parallel Group Study of the Efficacy and Safety of Tesevatinib in Subjects with Autosomal Dominant Polycystic Kidney Disease

2017-Continuing PI: Kianoosh Kaveh Relypsa AMBER Protocol RLY5016-207
A Randomized, Double-Blind, Placebo-controlled, Parallel Group Study of Patiromer for the Enablement of Spironolactone Use for Blood Pressure Control in Patients with Resistant Hypertension and Chronic Kidney Disease: Evaluation of Safety and Efficacy

2016 - continuing PI: Kianoosh Kaveh GSK ASCEND-D Protocol: 200807
A phase 3 randomized, open-label (sponsor-blind), activecontrolled, parallel-group, multi-center, event driven study in dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to recombinant human erythropoietin, following a switch from erythropoietin-stimulating agents.

2016 - continuing PI: Kianoosh Kaveh GSK ASCEND-ND Protocol: 200808
A phase 3 randomized, open-label (sponsor-blind), active-controlled, parallel-group, multi-center, event driven study in non-dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to darbepoetin alfa.

2014 - 2016 PI: Usha Chandrahassa ASTRAZENECA STRATOS-1 Protocol: D2210C00007
Sub-I: Kaveh, Pankhaniya & Hanumanthappa
A 52-Week, Multicentre, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Tralokinumab in Adults and Adolescents with Asthma Inadequately Controlled on Inhaled Corticosteroid Plus Long-Acting β_2 -Agonist

2015 - continuing PI: Kianoosh Kaveh ASTRAZENECA OLYMPUS Protocol: D5740C00001
Sub-I: Pankhaniya & Hanumanthappa
A phase 3, Multicenter, Randomized, Double-Blind, placebo- controlled Study Evaluating the Safety and Efficacy of Roxadustat for the Treatment of Anemia in Chronic kidney Disease Patients not on Dialysis

2014 – continuing PI: Rohit Pankhaniya JANSSEN CREDESCENCE Protocol 28431754DNE3001
Sub-I: Kaveh, Chandrahassa & Hanumanthappa
A Randomized, Double-blind, Event-driven, Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy

VOLUNTEER MEDICAL RESEARCH
3221 Tamiami Trail, 2nd Floor, Port Charlotte, FL 33952
Ph. (941) 258-3556 Fax (941) 258-3558

CV for Dr. Rohit Pankhaniya, MD

2014 - continuing **PI: Kianoosh Kaveh** **OTSUKA** **Protocol: 156-13-211**

Sub-I: Pankhaniya, Chandrasaha & Hanumanthappa

A phase 3b, Multicenter, open-Label Trail to Evaluate the Long Term Safety of Titrated Immediate-release Tolvaptan (OPC 41061, 30 mg to 120 mg/day, Split dose) in Subjects with Autosomal Dominant Polycystic Kidney Disease

2014 - 2017 **PI: Kianoosh Kaveh** **OTSUKA REPRISE** **Protocol: 156-13-210**

Sub-I: Pankhaniya & Chandrasaha

A Phase 3b, Multi-center, Randomized-withdrawal, Placebo-controlled, Double-blind, Parallel-group Trial to Compare the Efficacy and Safety of Tolvaptan (45 to 120 mg/day, Split-dose) in Subjects with Chronic Kidney Disease Between Late Stage 2 to Early Stage 4 Due to Autosomal Dominant Polycystic Kidney Disease

2014 – 2014 **PI: Usha Chandrasaha** **GENENTECH** **PROSPERO** **Protocol: ML28528**

Sub-I: Kaveh & Pankhaniya

A Prospective Observational Study to Evaluate Predictors of Clinical Effectiveness in Response to Omalizumab

2014 – 2016 **PI: Rohit Pankhaniya** **TAKEDA LN** **Protocol: MLN9708**

Sub-I: Kaveh & Chandrasaha

A Phase 1b, Randomized, Double-Blind, Placebo-Controlled, Safety, Tolerability and Pharmacokinetic Study of Multiple Rising Doses of MLN9708 for the Treatment of Subjects With ISN / RPS Class III or IV Lupus Nephritis

2014 – 2015 **PI: Kianoosh Kaveh** **GENKYOTEX** **Protocol: GSN000200**

Sub-I: Pankhaniya, Chandrasaha & Hanumanthappa

A Double-Blind, Randomized, Placebo-Controlled, Phase 2 Study Evaluating the Safety and Efficacy of Oral GKT137831 in Patients with Type 2 Diabetes and Albuminuria

2014- 2015 **PI: Rohit Pankhaniya** **TAKEDA** **Protocol: FEB-XR_301**

Sub-I: Kaveh, Chandrasaha & Hanumanthappa

A Phase 3, Randomized, Double Blind, Multicenter, Placebo Controlled Study to Evaluate the Efficacy and Safety of Febuxostat 40 mg XR, 80 mg XR, 40 mg IR and 80 mg IR in Subjects with Gout

2014- 2015 **PI: Rohit Pankhaniya** **TAKEDA** **Protocol: FEB-XR_201**

Sub-I: Kaveh, Chandrasaha & Hanumanthappa

A Phase 2, Randomized, Double Blind, Multicenter, Placebo Controlled Study to Evaluate the Efficacy and Safety of Febuxostat 40 mg XR, 80 mg XR, 40 mg IR and 80 mg IR in Subjects with Gout and Moderate Renal Impairment

2011 – 2015 **PI: Kianoosh Kaveh** **BI 1245.25 CASCADE** **Protocol: 1245.25**

Sub-I: Pankhaniya

A Phase III, multicenter, international, randomized, parallel group, double blind CV safety study of BI 10773 (10 mg & 25 mg administered orally once daily) compared to usual care in type 2 diabetes mellitus patients with increased CV risk.

VOLUNTEER MEDICAL RESEARCH
3221 Tamiami Trail, 2nd Floor, Port Charlotte, FL 33952
Ph. (941) 258-3556 Fax (941) 258-3558

CV for Dr. Rohit Pankhaniya, MD

2012 – 2018 **PI: Kianoosh Kaveh** **AMGEN** **START-CKD** **Protocol: 20110226**

Sub-I: Pankhaniya & Hanumanthappa

Strategies Using Darbepoetin alfa to Avoid Transfusions in Chronic Kidney Disease.

2010 - 2017 **PI: Kianoosh Kaveh** **TAKEDA** **CARES** **Protocol: TMX-67_301**

Sub-I: Pankhaniya & Hanumanthappa

A Multicenter, Randomized, Active-Control, Phase 3B Study to Evaluate the Cardiovascular Safety of Febuxostat and Allopurinol Subjects with Gout and Cardiovascular Comorbidities.

2011 – 2015 **PI: Kianoosh Kaveh** **OTSUKA** **TEMPO 4/4** **Protocol: 156-08-271**

Sub-I: Pankhaniya

A Multicenter, Open-Label, Extension Study to Evaluate the Long-Term Efficacy and Safety of Oral Tolvaptan Tablet Regimens in Subjects with Autosomal Dominant Polycystic Kidney Disease (ADPKD)

2013-2014 **PI: Rohit Pankhania** **AKEBIA THERAPEUTICS** **Protocol: AKB6548-CI-0007**

Sub-I: Kaveh

This is a Phase 2B Randomized, Double-Blind, Placebo-Controlled study to assess the Pharmacodynamic response, Safety, and Tolerability to 20 weeks of oral dosing of AKB-6548 in subjects with Anemia secondary to Chronic Kidney Disease (CKD), GFR categories G3A-G5 (Stages 3,4,and 5)(Pre-Dialysis)

2012 – 2014 **PI: Kianoosh Kaveh** **LILLY/ICON** **Protocol: H9V-MC-GFRF**

Sub-I: Pankhaniya

A Randomized, Double-Masked, Placebo-Controlled, Multicenter, Phase 2 Study to Evaluate the Safety and Renal Efficacy of LY2382770 in Patients with Diabetic Kidney Disease Due to Type 1 or Type 2 Diabetes.

2011 – 2014 **PI: Kianoosh Kaveh** **OTSUKA** **OVERTURE** **Protocol: 156-10-291**

Sub-I: Pankhaniya

A Multi-Center, Longitudinal, Observational Study of Patients with Autosomal Dominant Polycystic Kidney Disease (ADPKD) to Establish the Rate, Characteristics, and Determinants of Disease Progression

2013 – 2013 **PI: Kianoosh Kaveh** **RELYPSA** **Protocol: RYL5016-301**

Sub-I: Pankhaniya

A Two-Part, Single-Blind, Phase 3 Study Evaluating the Efficacy and Safety of Patiromer for the Treatment of Hyperkalemia

2013 – 2013 **PI: Kianoosh Kaveh** **GSK** **Protocol: PHI116581**

Sub-I: Pankhaniya

A Four Week Phase IIa, double-blind, placebo-controlled \, parallel-group, multi-center study to evaluate the safety, efficacy & pharmacokinetics of **GSK1278863** in subjects with anemia associated with chronic kidney disease who are not taking recombinant human erythropoietin and are not undergoing dialysis.

VOLUNTEER MEDICAL RESEARCH
3221 Tamiami Trail, 2nd Floor, Port Charlotte, FL 33952
Ph. (941) 258-3556 Fax (941) 258-3558

CV for Dr. Rohit Pankhaniya, MD

2011 – 2013 PI: Kianoosh Kaveh OTSUKA SALACIA Protocol: 156-08-275

Sub-I: Pankhaniya

A Phase 3b, Multicenter, Randomized, Single-blind, Parallel Group Trial of the Effects of Titrated Oral SAMSCA (Tolvaptan) 15, 30 or 60 mg QD Compared to Placebo Plus Fluid Restriction on Length of Hospital Stay and Symptoms in Subjects Hospitalized with Dilutional Hyponatremia. CLOSED BY SPONSOR

2011 –2012 PI: Rohit Pankhaniya ABBOTT RADAR Protocol: M11-350

Sub-I: Kaveh

Reducing Residual Albuminuria in Subjects with Diabetes and Nephropathy with AtRasentan - A Phase 2b, Prospective, Randomized, Double-Blind, Placebo- Controlled Trial to Evaluate Safety and Efficacy.

2011 – 2013 PI: Kianoosh Kaveh OTSUKA HYPONATREMIA REGISTRY Protocol: 156-10-292

Sub-I: Pankhaniya

An Observational Prospective Registry to Identify Demographic & Clinical Characteristics of Patients Hospitalized with Euvolemic & Hypervolemic Hyponatremia & Assess the Comparative Effectiveness of Available Treatments & the Impact on Resource Utilization.

2011 - 2013 PI: Kianoosh Kaveh REATA BEACON Protocol: 402 C 0903

Sub-I: Pankhaniya

Bardoxolone Methyl Evaluation in Patients with CKD & Type 2 DM: The Occurrence of Renal Events.
Study Terminated

2011 – 2012 PI: Rohit Pankhaniya TAKEDA Protocol: TAK-491 CLD_309

Sub-I: Kaveh

A Randomized, Open Label, Phase 3 Study to Compare Long Term Safety and Tolerability of the TAK 491 and Chlorthalidone Fixed Dose Combination vs Olmesartan Medoxomil and Hctz Fixed Dose Combination in Hypertensive Subjects with Moderate Renal Impairment.

2010 – 2012 PI: Rohit Pankhaniya TAKEDA Protocol: TMX-67_203

Sub-I: Kaveh

A Multicenter, Randomized, Double-Blind, Phase 2 Study to Evaluate the Effect of Febuxostat verses Placebo on Renal Function in Gout Subjects with Hyperuricemia and Moderate to Severe Renal Impairment”

2010 PI: Kianoosh Kaveh REATA Protocol: 402 –C – 0902

Sub-I: Pankhaniya

A Multi-Center, Open-Label, Randomized, Parallel Group, Dose-Ranging, Pharmacodynamic Phase II Trial to Determine the Effects of Bardoxolone Methyl (RTA 402, Amorphous Dispersion) on eGFR in Patients with Type 2 Diabetes and Chronic Kidney Disease (eGFR 15-45 L/min/1.73m²) **Closed**

VOLUNTEER MEDICAL RESEARCH
3221 Tamiami Trail, 2nd Floor, Port Charlotte, FL 33952
Ph. (941) 258-3556 Fax (941) 258-3558

CV for Dr. Rohit Pankhaniya, MD

2010 PI: Kianoosh Kaveh CARDIOKINE OLE Protocol: CK LX 3431

Sub-I: Pankhaniya

International, Multicenter, Study of the Twenty-Eight Week, Open-Label, Titrated Oral Lixivaptan Administration in Patients with Chronic Hyponatremia: Extension to Studies CK-LX 3401, 3405, and 3430
Closed

2010 PI: Kianoosh Kaveh CARDIOKINE HARMONY Protocol: CK LX 3430

Sub-I: Pankhaniya

Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Tolerability of Oral Lixivaptan Capsules in Subjects with Euvolemic Hyponatremia **CLOSED**

2009 – 2010 PI: Rohit Pankhania LUPITOLD REPAIR IDA Protocol: 1VIT09030

Sub-I: Kaveh

Randomized Evaluation of efficacy and safety of Ferric carboxymaltose in Patients with iron deficiency Anemia and Impaired Renal function.

2009 PI: Kianoosh Kaveh REATA BEAM Protocol: 402 C 0804

Sub-I: Pankhaniya

BEAM Study A 52-week, Multi-center, Double-blind, Randomized, Placebo-controlled Phase IIb Trial to Determine the Effects of **Bardoxolone Methyl (RTA 402)** on eGFR in Patients with Type 2 DM and CKD with an eGFR of 20-45 mL/1.73m². **Closed**

2008 PI: Kianoosh Kaveh CARDIOKINE BALANCE Protocol: CK LX 3401

Sub-I: Pankhaniya

Treatment of Hyponatremia Based on Lixivaptan in NYHA Class III/IV Cardiac Patient Evaluation. **Closed**

2008 PI: Kianoosh Kaveh ABBOTT Protocol: M10-313

Sub-I: Pankhaniya

A 30-Week, Multi-center, Randomized, Double-blind, Parallel-group Study of the Combination of ABT-335 and Rosuvastatin Compared to Rosuvastatin Monotherapy in Dyslipidemic Subjects with Stage 3 Chronic Kidney Disease. **Closed**

2008 PI: Kianoosh Kaveh AMGEN Protocol: 20070664

Sub-I: Pankhaniya

A Phase 2, Randomized, Double-blind, Placebo-controlled, Parallel Group, Fixed Dose Study of AMG 223 in Subjects with Chronic Kidney Disease on Hemodialysis with Hyperphosphatemia. **Closed**

2008 PI: Kianoosh Kaveh OTSUKA TEMPO ¾ Protocol 156-04-251

Sub-I: Pankhaniya

A Phase 3, Multi-center, Double-blind, Placebo-controlled, Parallel-arm Trial to Determine Long-term Safety and Efficacy of Oral Tolvaptan Tablet Regimens in Adult Subjects with Autosomal Dominant Polycystic Kidney Disease. **Closed**

VOLUNTEER MEDICAL RESEARCH
3221 Tamiami Trail, 2nd Floor, Port Charlotte, FL 33952
Ph. (941) 258-3556 Fax (941) 258-3558

CV for Dr. Rohit Pankhaniya, MD

2008 PI: Kianoosh Kaveh OTSUKA *INSIGHT* Protocol: 156-04-426

Sub-I: Pankhaniya

Pharmaceutical Development & Commercialization, Inc. A Pilot, Phase 3B, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel Group Study of the Effects of Titrated Oral Tolvaptan 15, 30, or 60 mg QD on Cognitive and Neurological Function in Elderly Hyponatremic Patients. **Closed**

2008 PI: Kianoosh Kaveh ASTELLAS PHARMA, US, INC. Protocol: YM087-CL-088

Sub-I: Pankhaniya

A Phase 3b, Randomized, Double-Blind, Parallel Group, Multi-Center Study to Assess the Efficacy and Safety of Multiple 30 Minute Infusions Of Conivaptan in Subjects with Euvolemic or Hypervolemic Hyponatremia. Site initiation August 2007. **Closed**

2008 AMGEN TREAT – Trial to Reduce Cardiovascular Events with Aranesp Therapy. Randomized, Double-Blind, Multicenter Study. AMGEN Phase III. Recruitment closed with 79 subjects screened and 50 enrolled. Completed enrollment placed Coastal Nephrology Associates Research Center first in the United States and second globally. **CLOSED Sub Investigator**

Rohit Pankhaniya, MD

Date