

**A multicenter, prospective, observational and single-arm interventional study of
mirogabalin in diabetic peripheral neuropathic pain: rationale and design of
Dia-NeP**

Hideki Kamiya^{1*}, Ryo Suzuki², Jun Wada³, Takahisa Deguchi⁴, Tatsuhito Himeno¹, Shuhei Yamamoto⁵, Taiki Toyama⁶, Jiro Nakamura^{1,7}

¹Division of Diabetes, Department of Internal Medicine, Aichi Medical University School of Medicine, Aichi, Japan

²Department of Diabetes, Metabolism and Endocrinology, Tokyo Medical University, Tokyo, Japan

³Department of Nephrology, Rheumatology, Endocrinology and Metabolism, Okayama University, Okayama, Japan

⁴Department of Diabetes, Metabolism and Endocrinology, Kagoshima University Graduate School of Medical and Dental Sciences, Kagoshima, Japan

⁵Data Intelligence Department, Daiichi Sankyo Co., Ltd., Tokyo, Japan

⁶Primary Medical Science Department, Daiichi Sankyo Co., Ltd., Tokyo, Japan

⁷Diabetes and Endocrinology Clinic TOSAKI Meito, Aichi, Japan

Corresponding author

Hideki Kamiya, MD, PhD

Division of Diabetes, Department of Internal Medicine, Aichi Medical University School of

Medicine, 1-1, Yazakokarimata, Nagakute, Aichi 480-1195, Japan

Tel: +81 561-62-3311

E-mail: hkamiya@aichi-med-u.ac.jp

Supplementary methods

The neuropathy questionnaire

Subjective Symptoms of Diabetic Neuropathy

Table 1. Neuropathy Questionnaire (to be filled out by the patient)

If the condition applies to both feet, consider it "Present," and if it applies to one foot, consider it "Absent."

	Question	Present	Absent
1	Do you have numbness*1 in the toes or soles of both feet?		
2	Do you feel both soles are somewhat covered with a thin layer of skin when you walk?		
3	Do you have pain*2 in the toes or the soles of both feet?		
4	Are your senses dull in the toes or the soles of both feet?		
5	Do your toes or soles of both feet feel hypersensitive, pain*2, or unpleasant when you touch them or when touched by something?		

*1 Numbness: numbness and a throbbing, tingling, or stinging sensation

*2 Pain: throbbing, tingling, stinging, stabbing, hot-burning, electric-shock, or aching pain

With regard to symptoms that the patient indicated as "present" in "Neuropathy Questionnaire (Table 1)," "Condition Item 1. Subjective Symptoms of Diabetic Neuropathy" in the "Brief Diagnostic Criteria for Diabetic Polyneuropathy of the Japanese Clinical Practice Guideline for Diabetes 2024" are coded as shown in the table below (Table 2), with DPN diagnosed according to "Brief Diagnostic Criteria for Diabetic Polyneuropathy of the Japanese Clinical Practice Guideline for Diabetes 2024".

Table 2. Neuropathy Interview Form (to be checked by the medical institution)

	Question	Subjective symptom		
		Numbness	Pain	Abnormal sensation
1	Do you have numbness*1 in the toes or soles of both feet?	☐		
2	Do you feel both soles are somewhat covered with a thin layer of skin when you walk?			☐
3	Do you have pain*2 in the toes or the soles of both feet?		☐	
4	Are your senses dull in the toes or the soles of both feet?			☐
5	Do your toes or soles of both feet feel hypersensitive, pain*2, or unpleasant when you touch them or when touched by something?		☐	☐

Supplementary Table S1. Full list of participating centers and investigators¹

Name of institution	Name of the principal investigator at the study site
Aichi Medical University Hospital	Hideki Kamiya ²
Okayama University Hospital	Jun Wada
Tokyo Medical University Hospital	Ryo Suzuki
Goshominami Harashima Clinic	Shinichi Harashima
Jiyugaoka Yamada Internal Medicine Clinic	Daishiro Yamada
Medical Corporation Tsurukamekai Shinjuku Tsurukame Clinic	Akio Kawakami
Yamashita Tsukasa Clinic	Tsukasa Yamashita
Medical Corporation Kensyoujukai Kumanomae Nishimura Internal Medicine Clinic	Hideki Nishimura
Kunisaki Makoto Clinic	Makoto Kunisaki
Yamagishi Clinic Sagamiono	Takahiro Yamagishi
TDE Healthcare Corporation TOSAKI Clinic for Diabetes and Endocrinology	Takahiro Tosaki
Medical Corporation Souaikai Aihara Medical Clinic	Kazuo Aihara
Oyama East Clinic	Kunihiro Suzuki
Sugawara Clinic	Masahiro Sugawara
Manda Memorial Hospital	Masahiko Kato
Hotaruno Hakuyukai Medical Corporation of Japan	Daigaku Uchida
Kumamoto Chuo Hospital	Kenro Nishida
Suruga Clinic	Akira Yamauchi
Saiseikai Kawaguchi General Hospital	Satoshi Tanaka
Takamatsu Red Cross Hospital	Tomoyo Oyama
Kameda Clinic	Masaki Miura
Nishiwaseda LifeCare Clinic	Kazuki Ikura
Dokkyo Medical University Hospital	Teruo Jojima
Yokkaichi Diabetes Clinic	Yohei Ejima

¹ As of February 21, 2025.² Principal investigator for this study.