

Optimal pharmacotherapy pathway in adults with diabetic peripheral neuropathic pain: the OPTION-DM RCT

Solomon Tesfaye,^{1,2*} Gordon Sloan,¹
Jennifer Petrie,³ David White,³ Mike Bradburn,³
Tracey Young,⁴ Satyan Rajbhandari,⁵
Sanjeev Sharma,⁶ Gerry Rayman,⁶ Ravikanth Gouni,⁷
Uazman Alam,^{8,9} Steven A Julious,¹⁰ Cindy Cooper,³
Amanda Loban,³ Katie Sutherland,³ Rachel Glover,³
Simon Waterhouse,³ Emily Turton,³
Michelle Horspool,¹¹ Rajiv Gandhi,¹
Deirdre Maguire,¹² Edward Jude,^{13,14}
Syed Haris Ahmed,^{8,15} Prashanth Vas,¹⁶
Christian Hariman,¹⁷ Claire McDougall,¹⁸
Marion Devers,¹⁹ Vasileios Tsalidis,²⁰
Martin Johnson,²¹ Didier Bouhassira,²²
David L Bennett²³ and Dinesh Selvarajah²
on behalf of the OPTION-DM group

¹Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, UK

²Department of Oncology and Human Metabolism, Medical School, University of Sheffield, Sheffield, UK

³Clinical Trials Research Unit, University of Sheffield, School of Health and Related Research (ScHARR), Sheffield, UK

⁴School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, UK

⁵Lancashire Teaching Hospitals NHS Trust, Chorley, UK

⁶East Suffolk and North Essex NHS Foundation Trust, Ipswich, UK

⁷Nottingham University Hospitals NHS Trust, Nottingham, UK

⁸University of Liverpool, Liverpool, UK

⁹Liverpool University Hospital NHS Foundation Trust, Liverpool, UK

¹⁰Medical Statistics Group, School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, UK

¹¹NHS Sheffield Clinical Commissioning Group, Sheffield, UK

¹²Harrogate and District NHS Foundation Trust, Harrogate, UK

¹³Tameside and Glossop Integrated Care NHS Foundation Trust, Ashton under Lyne, UK

¹⁴University of Manchester, Manchester, UK

¹⁵Countess of Chester Hospital NHS Foundation Trust, Chester, UK

¹⁶King's College Hospital NHS Foundation Trust, London, UK

¹⁷Royal Wolverhampton NHS Trust, Wolverhampton, UK

¹⁸University Hospital Hairmyres, East Kilbride, UK

¹⁹University Hospital Monklands, Airdrie, UK

²⁰Gateshead Health NHS Foundation Trust, Gateshead, UK

²¹hVIVO Services Limited, London, UK

²²Hospital Ambroise Paré, Paris, France

²³Nuffield Department of Clinical Neurosciences, University of Oxford, Oxford, UK

*Corresponding author solomon.tesfaye@nhs.net

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Plain English summary

The OPTION-DM RCT

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Plain English summary

The number of people with diabetes is growing rapidly in the UK and is predicted to rise to over 5 million by 2025. Diabetes causes nerve damage that can lead to severe painful symptoms in the feet, legs and hands. One-quarter of all people with diabetes experience these symptoms, known as 'painful diabetic neuropathy'. Current individual medications provide only partial benefit, and in only around half of patients. The individual drugs, and their combinations, have not been compared directly against each other to see which is best.

We conducted a study to see which treatment pathway would be best for patients with painful diabetic neuropathy. The study included three treatment pathways using combinations of amitriptyline, duloxetine and pregabalin. Patients received all three treatment pathways (i.e. amitriptyline treatment for 6 weeks and pregabalin added if needed for a further 10 weeks, duloxetine treatment for 6 weeks and pregabalin added if needed for a further 10 weeks and pregabalin treatment for 6 weeks and amitriptyline added if needed for a further 10 weeks); however, the order of the treatment pathways was decided at random. We compared the level of pain that participants experienced in each treatment pathway to see which worked best.

On average, people said that their pain was similar after each of the three treatments and their combinations. However, two treatments in combination helped some patients with additional pain relief if they only partially responded to one. People also reported improved quality of life and sleep with the treatments, but these were similar for all the treatments. In the health economic analysis, the value for money and quality of life were similar for each pathway, and this resulted in uncertainty in the cost-effectiveness conclusions, with no one pathway being more cost-effective than the others. The treatments had different side effects, however; pregabalin appeared to make more people feel dizzy, duloxetine made more people nauseous and amitriptyline resulted in more people having a dry mouth. The pregabalin supplemented by amitriptyline pathway had the smallest number of treatment discontinuations due to side effects and may be the safest for patients.

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