

「成人気管支拡張症患者におけるマクロライドおよび吸入抗菌薬の安全性と治療成績の国際評価 - GEMSTONE 試験」

に対するご協力をお願い

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このたび当院では上記の医学系研究を、慶應義塾大学医学部倫理委員会の承認ならびに研究機関の長の許可のもと、倫理指針および法令を遵守して実施します。今回の研究では、同意取得が困難な対象となる患者さんへ向けて、情報を公開しております。なおこの研究を実施することによる、患者さんへの新たな負担は一切ありません。また患者さんのプライバシー保護については最善を尽くします。本研究への協力を望まれない患者さんは、その旨を「8 お問い合わせ」に示しました連絡先までお申し出下さいますようお願いいたします。

1 対象となる方

本研究の対象となる方は、2000 年 1 月 1 日から 2023 年 12 月 31 日までの間に、長期（3 か月以上）のマクロライド系抗菌薬または吸入抗菌薬による治療を受けた気管支拡張症の患者さんです。診断は臨床的および画像的所見（胸部 CT など）によって行われております。年齢が 18 歳以上の方が対象となります。すでに診療を受けていらっしゃる方のうち、これらの条件を満たす方が本研究の対象です。

2 研究課題名

承認番号 20251094

研究課題名 成人気管支拡張症患者におけるマクロライドおよび吸入抗菌薬の安全性と治療成績の国際評価 - GEMSTONE 試験

3 研究組織

研究代表機関

IRCCS Humanitas Research Hospital

研究代表者

Respiratory Unit Physician Mattia Nigro

共同研究機関：文末に別紙添付する。GEMSTONE Participating center.pdf を同時に添付する。

4 本研究の目的、方法

本研究は、気管支拡張症の患者さんに対して、長期にわたりマクロライド系抗菌薬や吸入抗菌薬を使用した場合の有効性や安全性を評価し、よりよい治療法の選択や医療の質の向上に役立てること

を目的としています。本研究は、過去の診療記録などの既存情報を用いた後ろ向き観察研究です。新たな検査や治療は行わず、すでに診療を受けていらっしゃる患者さんの診断内容や治療経過、検査結果などの情報を匿名化したうえで収集し、解析します。収集した情報は、個人が特定されないよう厳重に管理し、研究以外の目的では使用いたしません。

5 協力をお願いする内容

本研究では、新たに検査や治療をお願いすることはありません。すでに診療の過程で記録されている診断や治療内容、検査結果などの情報を、個人が特定できない形で研究に利用させていただきます。ご協力いただくことによる費用のご負担や、診療に関する不利益は一切ありません。また、研究へのご協力を希望されない場合は、お申し出いただければご自身の情報が本研究に利用されることはありません。

6 本研究の実施期間

研究実施許可日～**2028 年 12 月 31 日**

7 外部への試料・情報の提供

本研究では、海外の共同研究機関であるイタリアの **IRCCS Humanitas Research Hospital** に情報を提供します。提供する内容は、診断や治療内容、検査結果などの診療情報ですが、すべて個人が特定できないように匿名化した情報のみを提供します。氏名や住所などの個人情報が外部に提供されることはありません。

8 お問い合わせ

本研究に関する質問や確認のご依頼は、下記へご連絡下さい。

また本研究の対象となる方またはその代理人（ご本人より本研究に関する委任を受けた方など）より、情報の利用や他の研究機関への提供の停止を求める旨のお申し出があった場合は、適切な措置を行いますので、その場合も下記へのご連絡をお願いいたします。

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（直通電話：03-5363-3793）月～金 9:00～17:00

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HUMANITAS

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