

Studie účinků ivermektinu na covid-19 byly špatně nadesignované i provedené, říká expert

epochtimes.cz/2024/04/05/studie-ucinku-ivermektinu-na-covid-19-nebyly-dobre-zkoncipovane-rika-expert/

Zdraví

Fotografie léku ivermektin prodávaného v 12mg tabletách, pouze na předpis lékařem. (The Epoch Times)



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„Je třeba financovat kvalitní, dostatečně robustní klinické studie s ivermektinem, aby bylo možné spolehlivě zmapovat jeho účinky při léčbě covidu-19,“ říká MUDr. Šimon Reich, který pracuje v oboru klinických studií. Podle něho nebyly dosavadní studie dobře designované a jejich výsledky vyvolávají podezření ze střetu zájmů.

Nedávno jsme [informovali](#) o tom, že americký Úřad pro kontrolu potravin a léčiv (FDA) stahuje negativní články o léčivé látce ivermektin ve spojení s onemocněním covid-19. FDA během pandemie vyzýval občany, aby jej přestali užívat k léčbě covidu, ale nyní některé články a posty na sociálních sítích po nátlaku lékařů stahuje.

V této souvislosti se široce diskutuje o cílené kampani, která měla během pandemie potlačit veškerá potenciální léčiva účinná proti novému viru SARS-CoV-2 a onemocnění covid-19, aby mohly být schváleny nové mRNA vakcíny v režimu „nouzového použití“. Dle amerických zákonů ([pdf](#)) je možné nouzové povolení udělit pouze pokud „neexistuje žádná vhodná, schválená a dostupná alternativa přípravku pro diagnostiku, prevenci nebo léčbu takového onemocnění nebo stavu“.

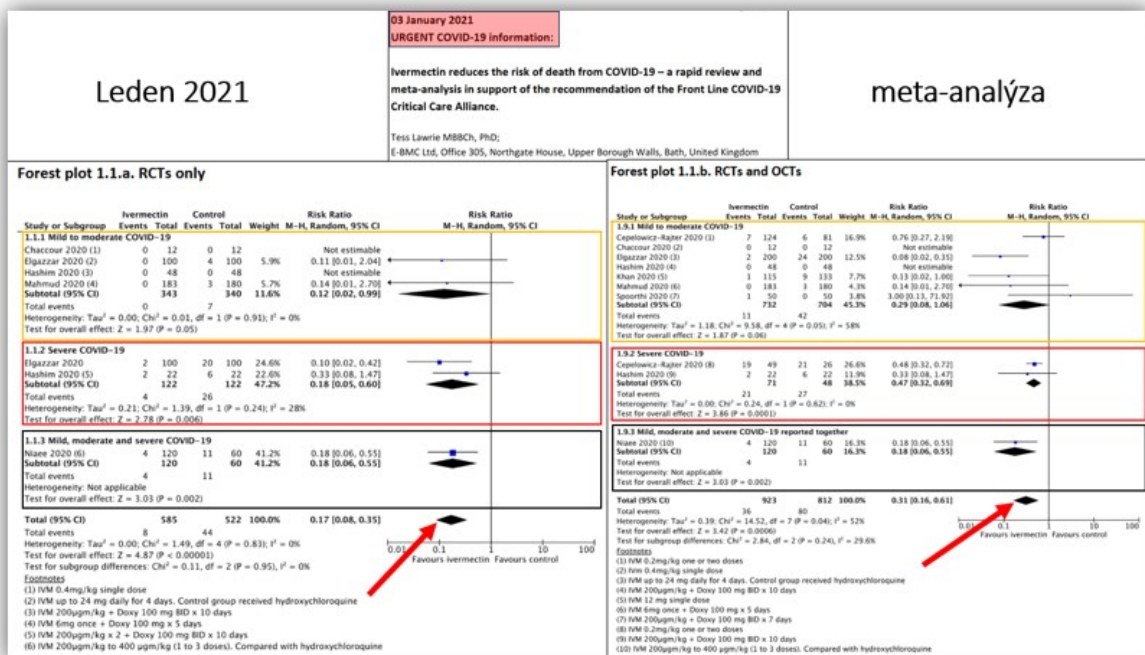
Stručně řečeno, pokud by bylo zjištěno, že nějaká látka účinně léčí onemocnění, nebylo by možné povolit nouzové použití vakcín.

Studie o účinnosti ivermektinu na covid-19

V České republice [povolilo](#) Ministerstvo zdravotnictví předepisovat ivermektin na léčbu covidu-19 na časové rozmezí od 12. března 2021 do 31. srpna 2021. Není nám prozatím známo, jak se vyhodnocovaly výsledky a jeho účinnost.

Podle MUDr. Šimona Reicha dospěla situace na jaře 2021 do bodu, kdy bylo dostatek informací na to, aby se začalo o využití ivermektinu během pandemie silně uvažovat.

„Tato meta-analýza randomizovaných a non-randomizovaných klinických studií za mě byla jasný signál, že pokud se do teď pochybovalo, tak nyní už je třeba ze strany států a státních institucí a organizací zafinancovat přípravu a průběh kvalitních, dostatečně robustních klinických studií s ivermektinem,“ sdělil Reich deníku *The Epoch Times*.



„Tuto meta-analýzu zpracovala důvěryhodná a nesmírně zkušená expertka Theresa Lawrie, která se živí tím, že podobné meta-analýzy zpracovává pro instituce jako WHO nebo Cochrane,“ dodává Reich.

Podle něho tkví problém částečně v tom, že nikdo, včetně originálního výrobce, který původně uváděl ivermektin na trh, neměl z byznysového hlediska žádnou motivaci financovat kvalitní studie, které by účinnost ivermektinu proti covid-19 mohly potvrdit.

Ivermektinu dávno vyprchala patentová ochrana a může ho proto vyrábět a prodávat každý. Jeho cena je dlouhodobě nízká a ani nová indikace tak nemůže vést k takovým ziskům jako jiné, docela nové léčivo pod čerstvou patentovou ochranou.

„Tvorba cen léčivých přípravků má svá specifická pravidla a je svým způsobem regulována,“ vysvětluje Reich. „Kromě toho se originální výrobce podílel na operaci *Warp Speed*, tedy na vývoji vakcín a nových preparátů proti covidu-19, v té době hojně financovaném vládou USA, což byl další důvod ivermektin přinejmenším ignorovat.“

Postupně se objevily „větší, vydatně zafinancované klinické studie“, které však podle Reicha vykazovaly problémy, které zkušený člověk z oboru může snadno vypožorovat. „Všechny tyto studie byly od začátku připravené tak, aby pokud možno vyzněly v neprospěch použití ivermektinu proti covid-19,“ míní Reich.



„Všechny velké, vydatně financované studie s ivermektinem nesou celou řadu znaků, které se tohoto týkají a v našem oboru se tomu říká *designed to fail*, studie od začátku připravená, navržená tak, aby neprokázala efekt studované intervence či preparátu.“

— MUDr. Šimon Reich, lékař

„Kdo v klinických studiích umí chodit a umí je do opravdu hlubokého detailu nastudovat, a správně je interpretovat, tak se všichni profesionálové, které znám, ale nevystupují v médiích, shodují na tom, že ivermektin funguje tak, že snižuje virovou nálož viru SRS CoV 2,“ říká Reich.

„Z toho vyplývá logická klinická úvaha, že například, když jsem se pohyboval mezi lidmi, kteří jsou pravděpodobně nakažení, tak to začnu brát, nebo ve chvíli, když vím, že jsem pozitivní a pravděpodobně infikovaný, tak to začnu brát. Čím později se ten preparát nasadí, tím horší má výsledky,“ popisuje účinky látky doktor Reich. „V pokročilém stavu těžkého covidu totiž odstranění původní příčiny – v tomto případě viru – už moc nepomůže bez ohledu na to, jaký preparát či preparáty pro to zvolíte.“

Jak „správně“ navrhnout studii

Studie, které se objevily, byly podle Reicha „nesmírně špatně nadesignované“ a také „nesmírně špatně až pochybně provedené“.

„Co-designoval (spolunavrhoval) jsem studie. Existují celé knihy pojednávající o tom, jak preklinickou nebo klinickou studii navrhnout a připravit tak, aby to pro váš preparát vyšlo pokud možno co nejlépe, ale stejným způsobem to lze udělat i naopak,“ vysvětluje postupy doktor Reich. „To znamená, že pokud chci, aby mi něco nevyšlo, tak jsou způsoby jak to udělat, abych zvýšil tu šanci, že mi tam efekt (preparátu) vyjde co nejmenší, přestože tam ten efekt třeba je.“

Všechny velké, vydatně financované studie s ivermektinem nesou podle Reicha „celou řadu znaků, které se tohoto týkají a v našem oboru se tomu říká *designed to fail* (navržená k neúspěchu)“.



„Ivermektin funguje tím způsobem, že snižuje virovou nálož viru SARS-CoV-2. Z toho logicky vyplývá, a ve studiích se to ukazuje, že nejvíce zabírá, když se užívá profylakticky (jako prevence nebo ochrana).“

— MUDr. Šimon Reich, lékař

Podle Reicha je též třeba sledovat autory studie a jejich vazby. „Jejich autoři byli lidé s obrovskými střety zájmů stejně jako i sponzoři těch studií, kteří měli vzhledem ke svým dalším investicím potenciální finanční zájem na tom, aby účinnost ivermektinu nevyšla,“ dodává Reich.

Dále nabízí přehled největších a „nejštedřejí zafinancovaných randomizovaných studií, které byly otisknuty v prestižních odborných časopisech s vysokým impakt faktorem“.

V níže uvedené tabulce popisuje v jakých aspektech byly studie špatně nastavené a odprezentované.

| Počet pracovišť | Počet pacientů | Hlavní autor/zkoušející studie | Zkrácené označení studie | Čas provedení studie | Pozdní publikace výsledků | Významné (známé) konflikty zájmů autorů studie | Sponzoři studie měli potenciálně finanční zájem na tom, aby se účinnost ivermektinu neprokázala | Nedostatečná síla z biostatistického hlediska pro klinicky významné parametry | Zásadní chyby v designu studie a/nebo jeho úprava v průběhu studie | Nevhodná populace pacientů | Pozdní nasazení, nedostatečná dávka a/nebo nedostatečně dlouhá terapie | Podání ivermektinu na prázdný žaludek | Znímký selhání randomizace | Nedostupnost důležitých výsledků a/nebo nemocita je poskytnout | Chybné závěry nebo opomenutí pozitivních výsledků |
|-----------------|----------------|--------------------------------|--------------------------|-------------------------------|------------------------------|--|---|---|--|----------------------------|--|---------------------------------------|----------------------------|--|---|
| 7x USA | 410 | Bramante | COVID-OUT | 01/2021 - 02/2022 (13 měsíců) | 08/2022 (10 měsíců zpoždění) | Very high | Yes | Very often | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 91x USA | 548 + 729 | Naggie | ACTIV-6 | 06/2021 - 02/2022 (8 měsíců) | 06/2022 (4 měsíce zpoždění) | Very high | Yes | Mostly | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 2x BRA | 679 | Reis | TOGETHER | 01/2021 - 08/2021 (7 měsíců) | 03/2022 (27 měsíců) | Very high | Yes | Very often | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 1x COL | 200 | Lopez-Medina | n/a | 07/2020 - 12/2020 (5 měsíců) | 04/2021 (4 měsíce) | Very high | Yes | Very often | Yes | Yes | Yes | Yes | No | Yes | |
| 7x UK | 2157 | Hayward | PRINCIPLE | 05/2021 - 07/2022 (14 měsíců) | 02/2024 (23 měsíců zpoždění) | Very high | Yes | Partially | Yes | Yes | Yes | Yes | No | Yes | Yes |

Jaké parametry by měla mít kvalitní studie

Níže uvádíme popis parametrizace kvalitní randomizované studie dle doktora Reicha a výčet studií:

1. populace pacientů 50+ let se středním až vysokým rizikem těžkého průběhu covid-19 (mladí, relativně zdraví pacienti se uzdravují dobře sami bez terapie a riziko středně těžkého či těžkého průběhu je u nich apriori malé = léčbu nepotřebují),
2. časně nasazení dostatečné dávky po dostatečně dlouhou dobu a dle váhy pacienta s jídlem (při podání s jídlem násobně stoupá absorpce léčiva do krve pacienta),

3. vstupní změření hladiny ivermektinu v plazmě (toto dnes již roli tolik nehraje, ale tenkrát ano, protože celá řada lidí v některých regionech ivermektin užívala ještě před tím, než vstoupila do studie),
4. opakované měření hladiny ivermektinu v plazmě v průběhu studie alespoň u části pacientů (kontrola, že pacienti ivermektin užívají tak, jak ho užívat mají).

Ani jedno se ani u jedné z výše uvedených studií nepovedlo, případně se proklamovalo, že se tak učinilo, ale z podrobnějšího studia dat jasně vychází, že se to nepovedlo (ať už z jakéhokoliv důvodu), konstatuje Reich.

Od začátku pandemie bylo celkem publikováno přes 160 originálních studií s ivermektinem



Zdravotnický pracovník ukazuje krabičku s lahvičkou ivermektinu v kolumbijském Cali 21. července 2020. (Luis Robayo / AFP via Getty Images)

- 27 in silico studií (počítačové simulace)^[1]
- 3 farmakokinetické studie^[2]
- 21 in vitro studií (laboratorní pokusy)^[3]
- 12 in vivo studií (pokusy na živých zvířatech)^[4]
- 49 klinických studií randomizovaných^[5]
- 56 klinických studií non-randomizovaných^[6]

Klinických studií bylo tedy publikováno přibližně 103, přičemž 86 těchto prací prošlo peer-review procesem (recenzním řízením).

S negativním závěrem je pouze 22 studií (nikoliv však nutně s negativními výsledky – ve skutečnosti tyto studie nezřídka obsahují celou řadu pozitivních nálezů, které hovoří pro účinnost ivermektinu), přičemž většina z nich obsahuje spoustu zásadních

chyb a rozporů, byly nečistoty připraveny a provedeny lidmi v gigantickém střetu zájmů, a je proto třeba je interpretovat velmi opatrně.

Bylo publikováno přibližně 18 přehledových článků a meta-analýz, drtivá většina z nich vyznívající pozitivně pro ivermektin.

Celkem bylo na téma ivermektin a jeho použití u onemocnění covid-19 publikováno více než 600 vědeckých článků.^[7]

Zdroje:

[1] In silico studie:

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[7] Celkový počet vědeckých článků na téma ivermektin a covid19:

The screenshot shows a PubMed search interface. At the top left is the PubMed logo. A search bar contains the text "Ivermectin AND covid" with a search button to its right. Below the search bar are links for "Advanced", "Create alert", "Create RSS", and "User Guide". A row of buttons includes "Save", "Email", "Send to", "Sort by: Most recent" (with a dropdown arrow), and "Display options" (with a gear icon). Below this is a section for "MY NCBI FILTERS" and a "705 results" indicator. A "RESULTS BY YEAR" bar chart shows a peak in 2020. The main result is a randomized trial titled "A randomized trial to assess the acceleration of viral clearance by the combination Favipiravir/Ivermectin/Niclosamide in mild-to-moderate COVID-19 adult patients (FINCOV)". The authors listed are Siripongboonsitti T, Tawinprai K, Avirutnan P, Jitobaom K, and Auewarakul P. The citation is "J Infect Public Health. 2024 Mar 29;17(5):897-905. doi: 10.1016/j.jiph.2024.03.030. Online ahead of print. PMID: 38569269". The background text states: "BACKGROUND: The efficacy of the viral clearance and clinical outcomes of favipiravir (FPV) in outpatients being treated for coronavirus disease 2019 (COVID-19) is unclear. Ivermectin (IVM), niclosamide (NCL),

SOUVISEJÍCÍ TÉMATA

[ivermectin](#)

SOUVISEJÍCÍ ČLÁNKY



[Vítězství žalujících lékařů: Úřad FDA odstranil kontroverzní prohlášení odrazující od použití ivermektinu k léčbě covidu](#)

[Zachary Stieber](#)



[Reakce českých expertů na dohodu mezi FDA a lékaři o odstranění negativních článků o ivermektinu](#)
[Milan Kajínek](#)



[Ivermektin by mohl být silným lékem v boji proti rakovině](#)
[Marina Zhang](#)



Jak úspěšný je ivermektin proti covidu-19? Hodnotí profesor Paul Marik. Detoxikace po covidu a po očkování

Jaroslav Pešta



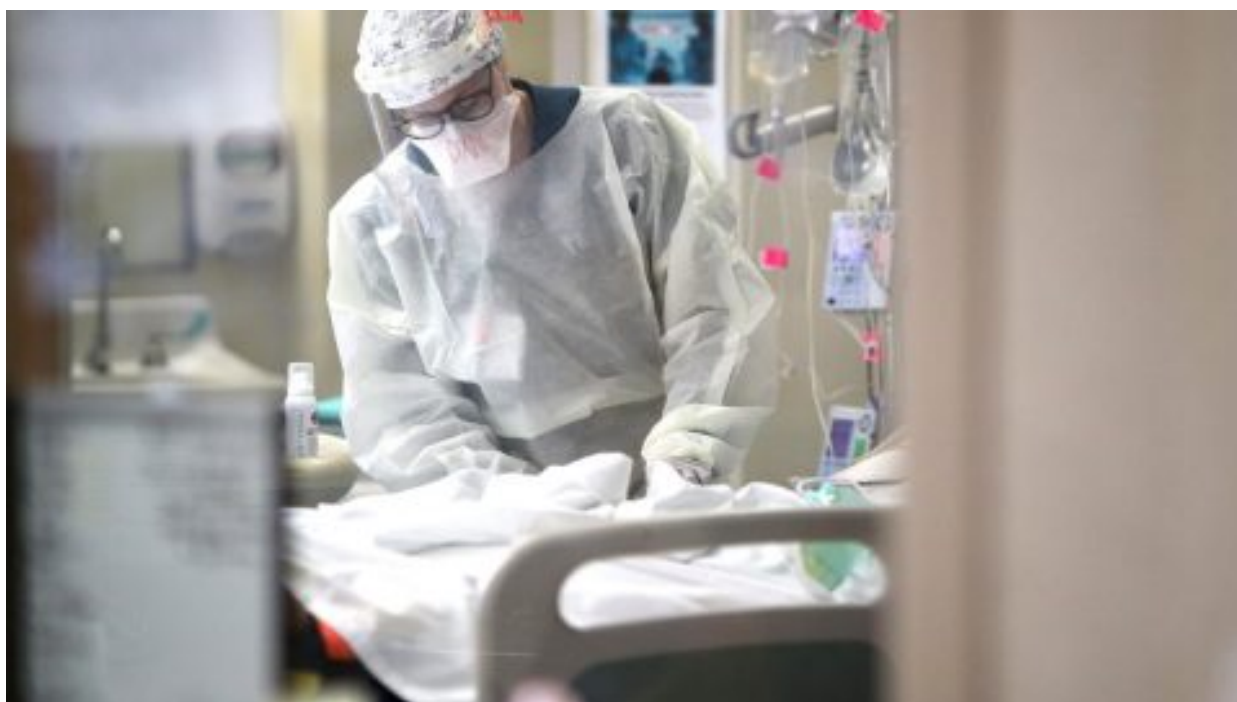
Top 10 covidových událostí roku: Odhalení nevyřčených a neznámých skutečností

Marina Zhang



[Právnička FDA: Lékaři mohou na covid-19 předepisovat ivermektin](#)

[Zachary Stieber](#)



[Covid se dá léčit včasnou léčbou, hlásí uskupení lékařů pomáhající nakaženým zdarma](#)

[Meiling Lee](#)

PŘEČTĚTE SI TAKÉ

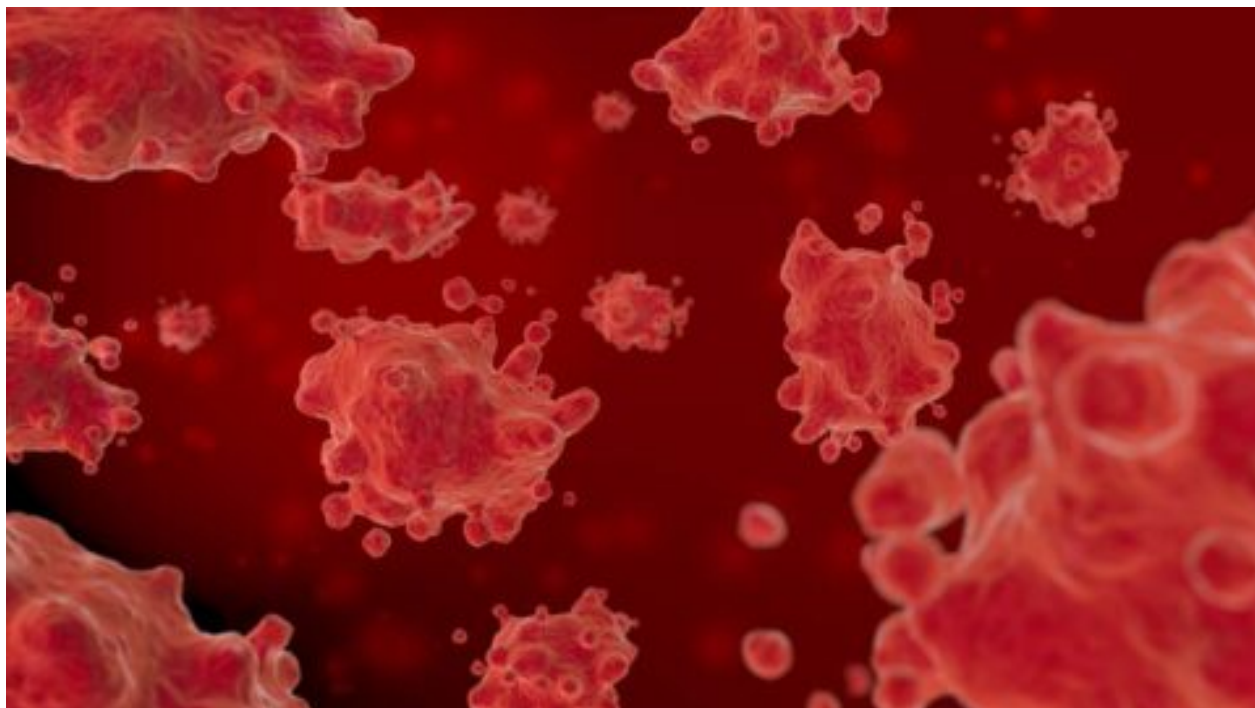


Liberecká policie pohotově pomohla v koloně rodičí ženě a nastávajícímu otci

Liberecká policie pomohla nastávajícím rodičům zaseknutým v koloně. Mezi máváním budoucího otce, doprovodu do nemocnice a narozením chlapečka uplynulo jen 10 minut.



Většina dětí z toho vyroste, uvádí nová studie o transgenderu



Studie: Stres způsobuje čtyřnásobně vyšší riziko vzniku rakoviny.



Zadlužení místních samospráv v Číně dosahuje krizových úrovní



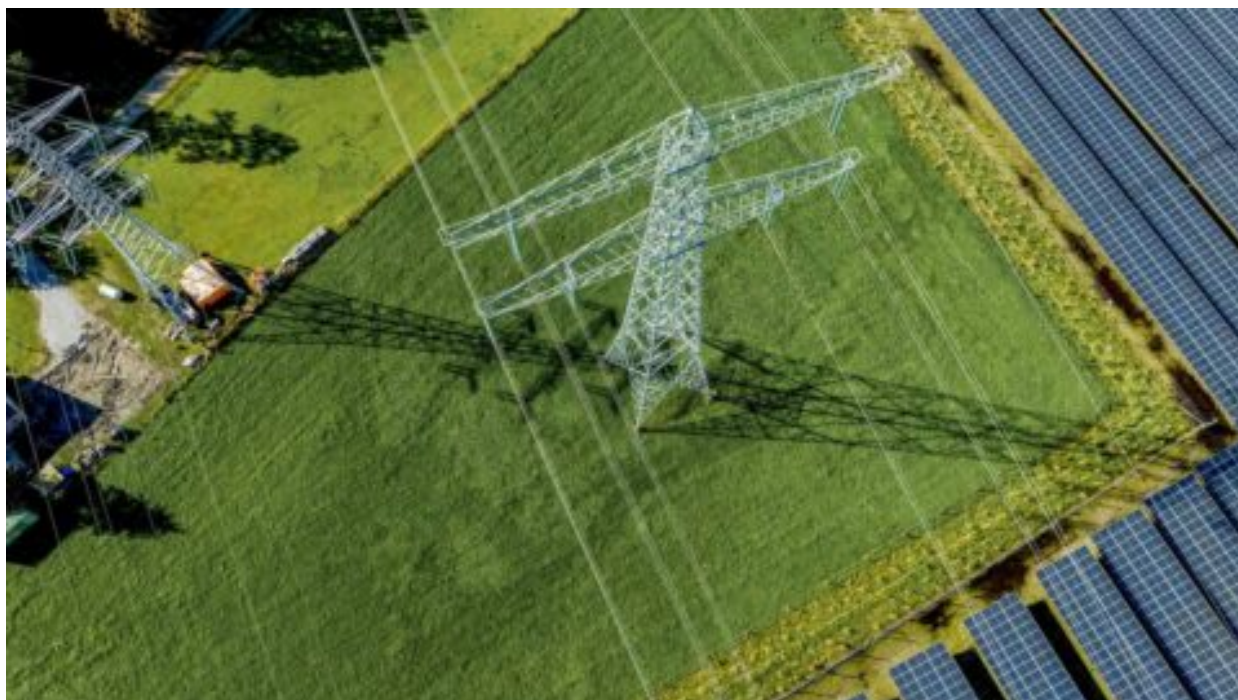
Nemáme v úmyslu poslat na Ukrajinu bojové jednotky NATO, uvedl Stoltenberg

Epoch sdílení

Nejčtenější články



Vrchní státní zastupitelství obdrželo trestní oznámení k očkování proti covidu-19



Exkluzivní rozhovor: Expert na elektrizační soustavu vysvětluje, jak nás zasáhne rozvoj solárních zdrojů



Zatímco EU je před zavedením e-peněženky, odborníci varují před „digitální cestou do pekel“ a omezením svobody.



Zmáčkne Putin červené tlačítko? Drábová promluvila o tématu hrozby nukleární války.

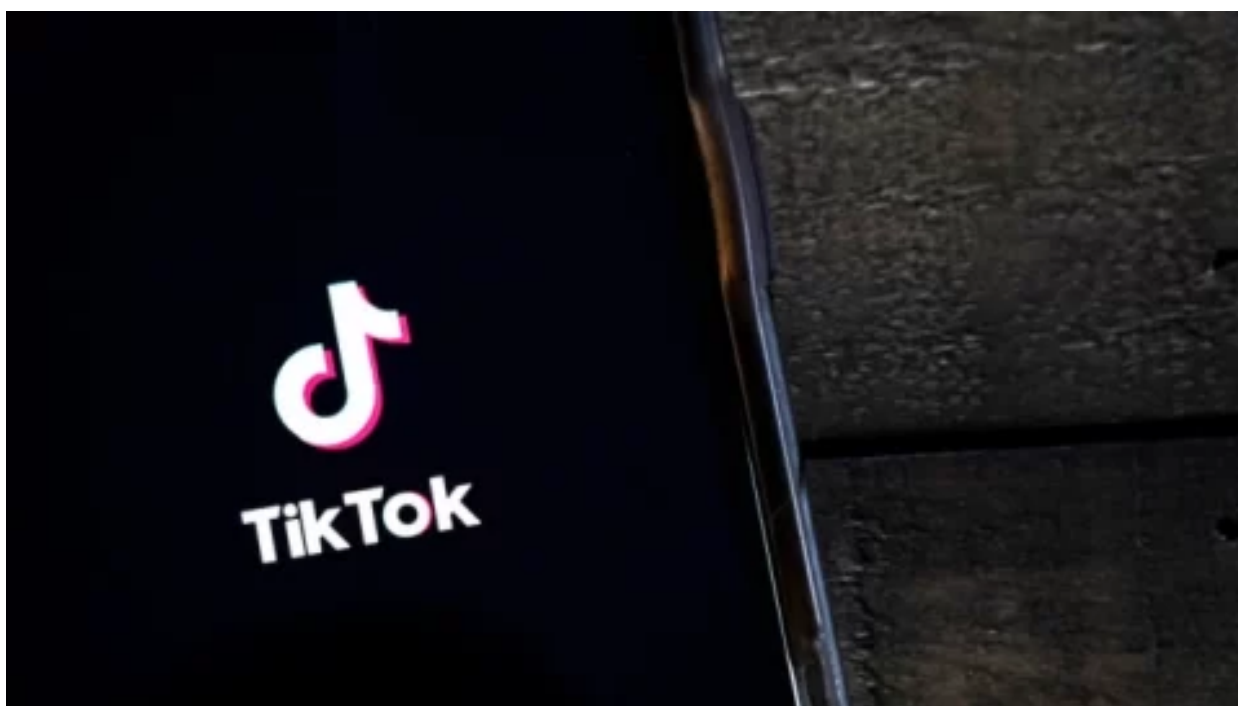


Pětičlenná rodina 4 roky téměř nenakupuje, přesto má dostatek jídla pro celý rok

Vybrané články



Výzkum: Wi-Fi a další elektromagnetická pole mohou souviset s neplodností a potraty.



TikTok: Čínský nástroj války.



Co jsme kdysi záviděli jim, nyní závidí nám. Brit varuje Čechy, aby si nenechali vzít svobodu projevu



Uhlí ve světě zdaleka nekončí. Rekordní poptávku táhne Asie



Bez uvedení telefonního čísla a e-mailu už ani do kina? Zkušenost spotřebitele

Více článků